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BIOMEDICAL RESEARCH TRAINING, AND MEDICAL LIBRARY ASSISTANCE AMENDMENTS OF 1983

MAY 16, 1983.—Ordered to be printed

Mr. HATCH, from the Committee of Labor and Human Resources, submitted the following

REPORT

[To accompany S. 773]

The Committee on Labor and Human Resources, to which was referred the bill (S. 773) to revise and extend programs relating to biomedical research, research training, and medical library assistance, to establish a National Institute of Arthritis and Musculoskeletal and Skin Diseases, and for other purposes, having considered the same, reports favorably thereon with amendments and recommends that the bill (as amended) do pass.

I. SUMMARY OF THE BILL

S. 773 amends the Public Health Service Act (PHSA) and makes additional provisions as follows:

(1) Reauthorizes for four years (through FY86), the National Cancer Institute, the National Heart, Lung, and Blood Institute, and the Medical Library Assistance Act. The authorization levels of FY83 are set at the levels appropriated in the continuing resolution for FY83 and are increased by five percent per year thereafter.

(2) Amends the National Cancer Institute legislation as follows:

(a) Requires Cancer Research and Cancer Control programs to include support for research projects related to "continuing care of the cancer patient and the patient's family."

(b) Authorizes Cancer Control programs to conduct "developmental research" in addition to current programs.

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(c) Highlights the International Cancer Research Data Bank and requests its continued maintenance and operation, focusing on dissemination of cancer research and treatment data.

(d) Requires the NCI Director to publicize widely the availability of NCI information on cancer.

(3) Increases the ceiling of direct costs from $35,000 to $50,000 on grants which may be approved by NCI and NHLBI without referral to the national advisory boards.

(4) Extends the grant cycle for Cancer Centers from three to five years.

(5) Extends through FY86 the authorization of appropriations for the Diabetes Data Group, the Diabetes Information Clearinghouse, and the Diabetes Research and Training Centers.

(6) Establishes in statute a National Kidney and Urologic Diseases Advisory Board, and authorizes the Diabetes, Kidney and Urologic Diseases, and Digestive Diseases Advisory Boards through FY86.

(7) Establishes in statute a National Institute of Arthritis and Musculoskeletal and Skin Diseases. Authorizes appropriations through FY86 for the National Arthritis and Musculoskeletal and Skin Diseases Data System, the National Arthritis and Musculoskeletal and Skin Dieseases Information Clearinghouse, Arthritis and Musculoskeletal Diseases Demonstration Projects, and Multipurpose Arthritis and Musculoskeletal Diseases Centers. Terminates the National Arthritis Advisory Board.

(8) Requires an external study to be conducted regarding the optimal administrative structure of the National Institutes of Health, and precludes any further legislative changes in the administrative structure of NIH prior to completion of this study and consideration by Congress. Also requires a review of the disease research programs within the National Institute of Diabetes and Digestive and Kidney Diseases.

(9) Authorizes appropriations through FY86 for digestive diseases research centers, and for the National Digestive Diseases Data System and the National Digestive Diseases Information Clearinghouse.

(10) Highlights the mental retardation research activities, including research centers, of the National Institute of Child Health and Human Development.

(11) Eliminates references to the Surgeon General which have been obsolete since 1966.

(12) Repeals payback requirements for the National Research Service Awards.

(13) Reauthorizes the National Research Service Awards for three years, through FY86.

(14) Requires an annual report regarding activities undertaken to improve grant, contracting, accountability, and peer review procedures at NIH.

(15) Requires Directors of NIH Institutes to notify their advisory boards of any investigation concerning any recipient of a grant or contract from NIH.

(16) Requires the Director of NIH to establish procedures for the appeal of determinations made on proposals for grants and contracts for biomedical research.

(17) Authorizes appropriations for a research center on the health effects of nuclear energy and other new energy technologies.

(18) Provides for expedited grant review procedures in case of public health emergencies, and authorizes administrative supplemental increases in relevant existing grants and contracts.

(19) Requires an external study to be conducted to assess the current status of the use of live animals in biomedical and behavioral research, and to explore the costs of upgrading federally-funded animal laboratories.

(20) Establishes several interagency committees on specific research-related problems, which are to report on their activities within eighteen months and then terminate:

(a) Interagency Committee on Learning Disabilities;

(b) Interagency Committee on Spinal Cord Injury;

(c) Subcommittee on Lung Diseases within the existing Interagency Technical Committee on Heart, Blood Vessel, Lung and Blood Diseases and Blood Resources; and

(d) Interagency Task Force on Alzheimer's Disease.

(21) Authorizes appropriations for FY84 for research grants on Alzheimer's disease.

(22) Requires a report on all NIH activities conducted during FY83 relating to alcoholism, alcohol abuse, and drug abuse.

II. Background and Need for Legislation

The Biomedical Research, Training, and Medical Library Assistance Amendments of 1983 revises and extends a number of programs under the Public Health Service Act (hereinafter referred to as the Act), primarily those relating to the National Institutes of Health (NIH). Renewed authorizations are provided for several programs whose authority expired at the end of fiscal year 1982 or will expire at the end of fiscal year 1983.

The National Institutes of Health is the principal medical research arm of the Federal Government. As one of the six health agencies of the Public Health Service, a component of the U.S. Department of Health and Human Services (DHHS), NIH has the mission of improving the health of the Nation by increasing our understanding of the processes underlying human health and by acquiring new knowledge to help prevent, detect, diagnose, and treat disease. The National Institutes of Health began as a one-room Laboratory of Hygiene established in 1887, and in the years since has grown to a complex of eleven research Institutes and associated support divisions and activities.

In reflection of the impact of disease on the health of the American people, the two largest of the research Institutes are the National Cancer Institute (NCI) and the National Heart, Lung, and Blood Institute (NHLBI). These two Institutes have in recent years received more congressional scrutiny than has the rest of NIH, including the need for periodic reauthorization. The other Institutes operate under the general research authority of Section 301 of the Public Health Service Act. This bill extends the funding for NCI and NHLBI for four years, through fiscal year 1986. The authorization levels for FY83 are set at the levels appropriated in the con-

tinuing resolution for FY83 and are increased by five percent per year thereafter.

In addition, the bill expands Cancer Research and Cancer Control programs to include support for research projects related to "continuing care of the cancer patient and the patient's family." Cancer victims and their families suffer tremendous psychological, economic, and social problems related to their illness. More research is needed on optimal care of the cancer patient during prolonged phases of illness and during terminal stages, and on psychosocial support of families, medical staffs, and patients. Cancer Control programs are authorized to conduct "developmental research" in addition to current programs. This will facilitate identification, field testing, and evaluation of cancer control methods and techniques. Continued maintenance and operation of the International Cancer Research Data Bank, authorized by the National Cancer Act of 1971, is mandated. A special focus is requested on dissemination of cancer research and treatment data, particularly through the use of information systems accessible to the public, general practitioners, and oncologic investigators. A newly-installed information system, called the Protocol Data Query (PDQ) system, will allow cancer patients and their physicians to obtain the latest information on cancer treatments, survival rates, and places where research is being carried on. The PDQ will serve as a link between community physicians, who initially see and diagnose most cancer patients, and the most up-to-date information on developments in cancer research. The grant cycle for cancer research and demonstration centers is extended from three years to five years. Finally, in both NCI and NHLBI, the Directors may approve grants without advisory board referral if the direct costs do not exceed $50,000 (instead of the current $35,000).

Another disease that brings great costs to our society is arthritis. In its more than 100 forms, arthritis and related musculoskeletal diseases afflict 35 million Americans, or 15 percent of the population. Not only the elderly are affected, but also adults in the prime of life and an estimated 250,000 children. The NIH research effort against arthritis is currently led by the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK), an entity with an extremely diverse set of research responsibilities. This bill divides NIADDK into two Institutes, creating a new National Institute of Arthritis and Musculoskeletal and Skin Diseases and renaming the balance of the Institute as the National Institute of Diabetes and Digestive and Kidney Diseases. Since much of the personnel and expertise necessary for the new Institute already exist in the NIADDK program, neither significant expense nor major alterations in administration will be needed. Several arthritis-related activities currently operating in NIADDK are reauthorized for three years, through FY86, under the new Institute. With appropriate changes in titles, these include the National Arthritis and Musculoskeletal and Skin Diseases Data System, the National Arthritis and Musculoskeletal and Skin Diseases Information Clearinghouse, Arthritis and Musculoskeletal Diseases Demonstration Projects, and Multi-purpose Arthritis and Musculoskeletal Diseases Centers. Creation of the new Institute will allow us to focus a

national effort on research for the prevention diagnosis, treatment, and eventual cure of arthritis and related debilitating diseases.

Within the newly-named National Institute of Diabetes and Digestive and Kidney Diseases (NIDDKD), several important research and information activities in the diabetes program require periodic reauthorization. The bill extends for three years, through FY86, the authority for the Diabetes Data Group, the Diabetes Information Clearinghouse, and the Diabetes Research and Training Centers. The reauthorization levels are equal to those for FY83.

Digestive diseases, ranging from the annoying to the life-threatening, cause chronic illness among 20 million Americans, according to the 1979 report of the National Commission on Digestive Diseases. They are the leading cause of hospitalization and the primary reason for major surgery in the United States, but research on the diseases is insufficient and epidemiological data on the specific disorders is inadequate. To extend the capabilities of the digestive diseases component of NIDDKD, the bill provides for the development and expansion of digestive diseases research centers and for the establishment of the National Digestive Diseases Data System and the National Digestive Diseases Information Clearinghouse. Three-year authorizations are provided for these activites.

The Advisory Boards within the National Institute of Diabetes and Digestive and Kidney Diseases play an important role in assuring the most effective use and organization of resources for research, treatment, education, and training in particular disease areas. This bill extends the authority for the National Diabetes Advisory Board and the National Digestive Diseases Advisory Board for three years, through FY86, and creates a National Kidney and Urologic Diseases Advisory Board, also authorized through FY86. The bill terminates the National Arthritis Advisory Board.

Spokesmen for numerous special interest groups press constantly for enhanced support for their particular areas, frequently calling for the creation of new programs or Institutes within the National Institutes of Health. In the quest to direct most fruitfully our limited research resources, it is prudent at this time to undertake a study of the administrative organization of NIH. The bill requires an 18-month study of the effectiveness of the current alignment of NIH Institutes and their disease responsibilities. No new Institutes beyond the new National Institute of Arthritis and Musculoskeletal and Skin Diseases are to be created until after completion of the study. At the same time, a special administrative review will be made of the disease research program within the National Institute of Diabetes and Digestive and Kidney Diseases.

Since the early 1960's, certain centers established under the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963 (P.L. 88–164) have been conducting research on the causes, prevention, and treatment of mental retardation. The centers were created to attract top scientists into long-term research work on mental retardation. The program has been very successful and has resulted in significant gains in our understanding of mental retardation. The bill directs that the National Institute of Child Health and Human Development make grants to these centers, and also adds research on mental retardation to the statement of purpose of the Institute.

The National Research Service Awards (NRSAs) are for the training of biomedical and behavorial scientists in areas of national need, and take the form of both individual fellowships and institutional fellowships ("training grants"). This bill extends the authorization of appropriations for the program for three years, through FY86, and also eliminates the payback requirement for recipients of the awards. In 1974 the Congress revised research training authorities and provided specific authorization ceilings. The legislation also included a service payback condition, presumably to make it less susceptible to Presidential disapproval and more acceptable to the public at large. Specifically, the payback requirement was seen as a means of preventing misuse of the research training program by individuals seeking subspecialty medical training. Currently, upon completion of training under the program, individuals who receive NRSA support are expected to engage in biomedical research or training for a period equal to the period of support. If an individual fails to fulfill the full service or "payback" obligation, the Federal Government is entitled to recover the stipend the individual received from the NIH plus interest beginning not later than two years after the award has terminated. The payback provision has been cited as one important factor in discouraging young physicians from embarking on a career in research, particularly those who are unsure whether they wish to pursue that course. In addition, because of this provision, the Internal Revenue Service has ruled that the awards are fully taxable, further discouraging potential researchers from devoting time to training.

A four-year renewal of authority through FY86 is made for the Medical Library Assistance Act program of the National Library of Medicine. Since its original passage in 1965, this Act has provided assistance through grants and contracts to health sciences libraries for library resources, research in biomedical communications, training, biomedical publications, and for the support of the Regional Medical Library Network. The activities supported under the Act have resulted in the improvement of medical library services, particularly by fostering cooperation and resource sharing.

The Secretary is required to prepare and transmit to the appropriate Senate and House Committees an annual report on activities undertaken to improve grant, contracting, accountability, and peer review procedures at NIH. Several recent instances of questionable research practices, and in some cases accusations of outright fraud, have led to congressional oversight hearings and a good deal of unfavorable media coverage. It is important that both the scientific community and the public be able to trust the uprightness and impartiality of research sponsored by NIH. Likewise, procedures for application, peer review, and approval of grants and contracts warrant continued discussion to insure their fairness to all potential applicants.

A requirement is placed on the Institute Directors to notify their Advisory Boards of the status of any investigation of a grant or contract recipient, unless such a disclosure would jeopardize the investigation. With such knowledge, the Board could make a more informed decision on any other applications the individual might have pending for approval.

A final provision concerning grants and contracts is that the NIH Director shall establish procedures for tne appeal of determinations made on applications for research funding. Currently, such procedures are not uniform among the various Institutes.

The development of new energy technologies will continue to be important to our Nation in the coming years, but much research remains to be done on the health effects of some of these technologies. Local communities hosting such new programs will need information on possible adverse health effects, or conversely, they will want to know that research has determined that health risks are minimal. Information of this nature is especially critical when dealing with nuclear energy technologies. This bill directs the Secretary of DHHS to make a grant to an academic institution to establish an independent research center on the health effects of nuclear energy and other new energy technologies, and authorizes funding for such a center for FY84 and subsequent years.

From time to time in recent years, new diseases or patterns of illness have appeared suddenly in segments of the population. Examples are Legionnaire's disease, toxic shock syndrome, and acquired immunodeficiency syndrome (AIDS). Frequently the public health community has no immediate explanation for the outbreaks and must commerce broad-ranging epidemiological and laboratory studies to define the problem. In the face of such public health emergencies, research efforts must be intensified quickly, including basic research that may bear on the problem. The normal peer review processes of approving applications for grants and contracts may be too slow. The bill authorizes the Secretary, after consultation with the heads of NIH, the Food and Drug Administration, and the Center for Disease Control, to determine that a disease or disorder constitutes a public health emergency and to expedite the review process for research applications dealing with the disease. The Secretary is also authorized to provide administrative supplemental increases in relevant existing grants and contracts.

The use of live animals in biomedical and behavioral research has sparked a great deal of controversy between research scientists and groups concerned about the welfare of laboratory animals. While some claim that mistreatment and unnecessary killing of animals is widespread, it is presently unclear just what the extent of the problem may be in federally-funded research facilities. Proposals to upgrade animal laboratories to meet certain standards could prove very costly, perhaps diminishing the overall research effort. It is also not clear what alternatives to the use of animals should be promoted. In light of these uncertainties, the bill provides for a comprehensive assessment of the current status of the use of live animals in research. The 18-month study will provide the Congress with information necessary before considering any further Federal legislation.

The bill provides for the establishment of several interagency committees on specific research-related problems. The information gathered by the committees in the course of 18 months will help the Congress determine whether any major changes are needed in the statute authorizing NIH. The following committees are provided for:

(1) The Interagency Committee on Learning Disabilities will serve to coordinate all physiological research on these common handicaps, which reportedly afflict over 15 million of our citizens, both children and adults. Misdiagnosis and misinformation about effective therapies for learning disabilities are common. The work of the committee should improve public information and the efficient use of Federal research funds directed toward these problems.

(2) The Interagency Committee on Spinal Cord Injury, made up of representatives of all the Federal agencies conducting or sponsoring research on spinal cord injury, will be required to document existing research efforts and develop a plan for long-term coordination among the agencies. Paralysis from a spinal cord injury is one of the most devastating things that can befall a person. Each year, some 20,000 individuals fall victim to such injuries, and in total, more than 500,000 Americans are affected. The economic costs, both to the individual's family and to the Nation, are staggering. Great benefits may be gained if a well-coordinated research program can make progress against paralysis and its complications.

(3) Within the existing Interagency Technical Committee on Heart, Blood Vessel, Lung and Blood Diseases and Blood Resources, a new subcommittee on lung diseases will develop a coordinated plan for the programs and activities of the various Institutes and agencies involved in lung disease research. Lung diseases are a major health problem in the United States, with one of every five persons reporting chronic respiratory symptoms. Many Federal research agencies expend a portion of their funding on programs which are in whole or in part lung related. The subcommittee will provide a specific mechanism for overviewing such research efforts, preventing duplication or omissions of important areas of investigation, and developing improved management approaches for lung disease research.

(4) The Interagency Task Force on Alzheimer's Disease will coordinate and review Federal agency research efforts on Alzheimer's disease, conduct public awareness activities, and develop a research strategy and plan for increased research, especially basic science research, on the disease. Funding for research grants is authorized for FY84. Alzheimer's disease is a progressive disorder of the brain affecting memory, thought, and language. Eventually the victim becomes incapable of taking care of himself and communicating his needs to others. Much more research is needed on the causes and progression of the disease, and on better methods of diagnosing and treating it. As the average age of our population increases, Alzheimer's disease will claim more victims, cause great suffering to millions of families, and be a costly drain on society's resources.

Federal research efforts on alcoholism and drug abuse are concentrated in the Alcohol, Drug Abuse, and Mental Health Administration of the Public Health Service. However, since substance abuse, particularly alcoholism, is a major cause of disability and death in our country, NIH should also be concerned with research progress in this area. The bill directs the Secretary to prepare a report on all NIH activities conducted during fiscal year 1983 relating to alcoholism, alcohol abuse, and drug abuse, specifying the number and type of personnel involved in such activities.

A final provision of the bill, not related to NIH, amends Title XIII of the Public Health Service Act to allow health maintenance organizations to use the services of clinical psychologists when applicable State law permits. Other health care personnel such as dentists, optometrists, and podiatrists are already covered under similar provisions.

III. History of S. 773

A bill, S. 773, to revise and extend programs relating to biomedical research, research training, and medical library assistance, to establish a National Institute of Arthritis and Musculoskeletal and Skin Diseases, and for other purposes was introduced by Senator Hatch on March 11, 1983, and was referred to the Committee on Labor and Human Resources.

A similar bill, S. 2311, was considered by the Committee during the 97th Congress and reported to the Senate May 28, 1982 (S. Rept. 97-461). Holds were placed on the bill and it was not brought up for consideration by the Senate. A separate bill to establish a National Institute of Arthritis and Musculoskeletal and Skin Diseases (S. 1939, introduced by Senator Goldwater), was passed by the Senate at the end of the 97th Congress. The Committee had held a hearing on the bill July 20, 1982; on December 21, 1982, the bill was discharged from the Committee by unanimous consent and was passed, amended, by the Senate. In the House, a unanimous consent request to consider the measure was rejected and the bill was not considered further.

On March 23, 1983, the Committee requested comment on S. 773 from the Department of Health and Human Services, the General Accounting Office, and the Office of Management and Budget.

On April 13, 1983, the Committee met in open executive session to consider an amended version of the bill which incorporated the recommendations and comments of members of the Committee, professional societies, the Administration, and interested individuals. During the session, Senator Metzenbaum offered an additional amendment establishing an Interagency Task Force on Alzheimer's Disease and authorizing appropriations for research on Alzheimer's disease. The amendment was adopted by the Committee, and the bill as amended was ordered reported favorably to the Senate.

IV. Hearing

A public hearing on S. 773 was conducted by the Committee on March 17, 1983, with the following individuals providing testimony:

Dr. Edward M. Brandt, Assistant Secretary for Health, Department of Health and Human Services; Dr. James Wyngaarden, Director, National Institutes of Health; Dr. Vincent DeVita, Jr., Director, National Cancer Institute; Dr. Claude L'Enfant, Director, National Heart, Lung, and Blood Institute; Dr. Lester Salans, Director, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases; Dr. Martin Cummings, Director, National Library of Medicine.

Dr. Timothy Talbot, Director, Fox Chase Cancer Center; Dr. Samuel Fox, III, American College of Cardiology; Dr. John Dixon,

National Digestive Diseases Advisory Board; Dr. Ephraim Engleman, Arthritis Foundation.

Dr. Chase Peterson, representing the Association of American Universities and the Association of American Medical Colleges.

V. Committee Views on S. 773

GENERAL

The Committee has spent considerable time and effort preparing for the reauthorization of the National Cancer Institute (NCI), the National Heart, Lung, and Blood Institute (NHLBI), and the National Library of Medicine Assistance Act. These two institutes, the only ones requiring periodic reauthorization, are the largest of the 11 National Institutes of Health. However, the Committee has used this legislation as an opportunity to consider programs and activities throughout the National Institutes of Health. Consequently, it is intended that these Committee views be considered relevant for all NIH programs, unless otherwise specified.

The National Institutes of Health are indisputably the premier biomedical research complex in the world. Their leadership in medical science developed through the 1960's, and their accomplishments have been translated into improved health care not only for our citizens, but also for mankind in general. Acquisition of new knowledge through basic biomedical research, clinical research, and promotion of that knowledge through technology transfer has improved the quality and longevity of life. The Committee views the government's investment in NIH programs as a highly appropriate federal effort, that overall has proven cost effective. Continuity in the federal investment is a key factor in attracting bright and capable young scientists to the field of medical science. Accordingly, the Committee emphasizes the need to maintain the current research effort to ensure that the momentum of expanding research efforts in the 1960's not be lost.

Thus, the Committee has authorized funding of the NCI and NHLBI programs at 5 percent over the fiscal year 1983. This level of funding will undoubtedly impose some constraints on new research efforts but should provide the resources to maintain a firm basis of support. The Committee recommends a similar increased level of support for the other institutes and programs at NIH.

Despite the strong support of the Committee for NIH, the Committee recognizes problems do exist. Congressional hearings and investigations over the previous decade have highlighted numerous concerns, many of which have persisted and, unfortunately, become even more troublesome. Those declared important by the Committee in the 97th Congress were specified in Report 97-461 accompanying S. 2311, the Biomedical Research, Training, and Medical Library Assistance Amendments of 1982. During hearings on S. 773, (March 17, 1983), the Chairman requested the Administration provide the Committee with an update on activities and efforts to address the particular problems cited in the 1982 Committee report. The full response of DHHS is printed herewith:

FRAUD AND ABUSE

"recent publicity regarding poor management and fraud among scientists whose research is supported by NIH" (p. 11, Senate Report 97-461)

A PHS task force to look into this issue developed a statement of general PHS policies and principles, which the Secretary has recently signed. This document provided two policy statements:

> It is the policy of the PHS to maintain high ethical standards in research and to investigate and resolve promptly and fairly all instances of alleged or apparent misconduct.
>
> The scientific community is expected to make every effort to prevent misconduct. Also, for every incident of alleged or apparent misconduct which is judged to warrant investigation by an awardee institution, that institution is expected to report on the matter to the head of the appropriate PHS agency/office or that agency's/office designee in accordance with PHS reporting requirements.

Possible sanctions for misconduct, depending upon the severity of the case, were also included as follows: actions with respect to present or future grant and/or contract awards (e.g., imposition of special conditions, termination, recommendation for debarment or suspension); regulatory actions (e.g., disqualification); and in the case of intramural research programs, termination of employment or other disciplinary action.

In addition, responsibilities for action were assigned as follows:

> The NIH Associate Director for Extramural Research and Training was designated as the PHS official responsible for developing, assessing, overseeing, and coordinating relevant policies and procedures.
>
> Agency heads were assigned to ensure appropriate implementation of policies and procedures to make decisions about appropriate sanctions to be applied, and to designate appropriate officials within the agency to handle matters related to misconduct in science.

The PHS committee is currently working on more detailed procedures for awarding agencies, regulatory components, and intramural research programs, as well as more formalized processes for information sharing and joint investigations.

PEER REVIEW SYSTEM

"persistent allegations that the peer review system is inefficient and sometimes unfair, in spite of multiple efforts in recent years to evaluate and improve the system" (p. 11, Senate Report 97-461)

The peer review system has responded to unprecedented demands by the scientific community by processing and reviewing increased numbers of applications over the period of the seventies and early eighties. The Division of Research Grants (DRG) has central operational responsibility for most of the system. The DRG currently operates 63 regularly chartered study sections comprised of more than 1100 members. In addition, it manages the Special Study Section, which conducts customized reviews of applications not appropriately reviewed ir regular study sections.

As resources necessary to award grants in proportion to the application rate have dwindled, changes have occurred in the behavior of the peer review system, as well as in the applicant community, although a cause and effect relationship remains to be proven. Some of these changes are:

(a) The rate of recommendations for approval for new research project applications increased from 62 percent in 1972 to 80 percent in 1982. The comparable rate for competing continuation applications has increased from 86 percent to 96 percent over the same period.

(b) The award rate for these applications has decreased over the same period from 52 percent to 28 percent in the case of new applications and from 68 percent to 48 percent in the case of competing continuation applications.

(c) Median priority scores for all competing research project applications recommended for approval have increased (become poorer) from 217 in 1972 to 225 in 1982, while those for applications actually awarded have decreased (improved) from 186 in 1972 to 159 in 1982.

(d) The number of investigators seeking R01 grant support for the first time continues to increase. For instance, in 1980, there were 3081 first-time applicants as compared to 1744 in 1970.

As the number of unfunded applicants has mounted, criticisms leveled at the peer review system have intensified. The two principal criticisms are that the same people continue to serve as study section members and that study section members are not as well qualified as they were in the past. Actually, about 85 percent of all study section members are serving their first appointment at any one time. Further, priority scores and approval rates for study section members' applications are both very much better than those of the general applicant population.

New prinicpal investigators (PIs) on NIH R01 projects continue to enter into the NIH research grant support system at an average annual rate greater than 10%. In the past five years the entry rate has averaged over 12%. Nearly a third of all competing PIs awarded each year are new; more than half of all new projects awarded each year are to scientists supported for the first time as principal investigators on NIH research grants. In fact, new applicants seeking support for their research as PIs on new research projects succeed at rates greater than other applicants who have applied previously.

These statistics belie the argument that the peer review system perpetuates the continued support of a select group of repeat investigators. Indeed, the facts substantiate that the system is coping very effectively with an increasing number of applications. However, despite all precautions, some inequities may occur. For this reason, in 1980 NIH established a formal procedure for handling commentaries and rebuttals to peer reviewers' evaluations. Another procedure used to strengthen the system is to convene a special review group for the occasional application that concerns an area of science not well represented on any study section.

"increase in indirects costs . . . and an Administration proposal that indirect costs be cut 10 percent across the board" (p. 11, Senate Report 97-461)

"the Committee expects the Department to renegotiate [indirect cost] rates on an institution-by-institution basis" (p. 73)

As a consequence of the directive in this Report and directives from the Appropriations Committees, NIH will reimburse indirect costs in full in FY 1983.

In addition, NIH and PHS officials have consulted with the research institution community in developing a report to be submitted shortly to the Appropriations Committees. The report will make a number of alternative recommendations for dealing with the question of indirect cost reimbursement.

The recommendations include the following:

Fixed-allowance reimbursement, based on the historical indirect cost/total cost level for each institution;

Across-the-board reduction in indirect costs;

Redefinition of reimbursable indirect costs;

Establishment of a standard fixed allowance; and

Choice of a fixed allowance or a negotiated rate, for each institution.

"inadequate research in preventive medicine and health promotion" (p. 11, Senate Report 97-461)

Current NIH expenditures for prevention research are listed below.

PREVENTION RESEARCH

[Dollars in thousands]

	1980 actual	1981 actual	1982 actual	1983 estimate	1984 request
Cancer	$123,179	$127,454	$132,869	[1]$94,845	$98,639
Heart	117,072	120,707	121,705	124,000	125,500
Dental	6,921	6,267	6,878	7,703	8,627
Arthritis	17,710	19,438	[2]28,474	32,000	32,500
Neurology	25,101	27,664	29,907	33,257	37,362
Allergy	27,480	32,948	[3]30,345	35,758	37,183
General Medical Science	6,041	5,705	[4]2,728	2,750	2,800
Child Health	85,373	86,710	94,958	108,800	112,100
Eye	29,612	31,263	36,537	40,884	42,151
Environmental Health	45,754	54,390	[2]82,582	[1]137,954	142,421
Aging	13,502	16,340	17,650	20,451	20,610
Research Resources	6,539	10,086	14,670	16,822	18,175
Fogarty	2,175	3,444	3,249	3,573	3,864
Total, NIH	506,459	542,416	602,552	658,797	681,932

[1] Transfer of national toxicology program to NIEHS from NCI—$47,988.
[2] Increase over 1981 reflects a re-evaluation of reportable prevention efforts, which has resulted in an increase of funds reportable for prevention research.
[3] Reduction in collaborative intramural program.
[4] Iatrogenic diseases are no longer included as prevention research.

Prevention research, for the purposes of this table, includes intervention before the biologic onset of the disease in question (e.g., reduction of dust levels in occupational settings), basic research directly relating to development of preventive measures, and direct

preventive measures themselves (such as vaccination programs, regulatory activities, and public education).

Included also are epidemiologic studies allowing for the identification and quantification of risk factors relating to personal characteristics such as habits associated with diet, use of cigarettes, alcohol consumption, exercise, and the like. Also included is the treatment of various biological conditions and risk factors such as elevated cholesterol and blood pressure levels and cigarette smoking to prevent cardiovascular complications such as myocardial infarction and stroke as well as chemoprevention, where there is a population with disease but not frank carcinoma that is being treated with chemoprevention (e.g., patients with leukoplakia being treated to prevent oral squamous cell carcinoma).

RARE DISEASE RESEARCH

"disproportionate funding of rare diseases processes (p. 11, Senate Report 97-461)

Research in rare diseases, as in all other areas, is predicated upon basic scientific opportunities, and the funding of particular studies is dependent on the excellence of the proposals. In the case of many rare diseases, an insufficient understanding of the underlying mechanism of disease often exists and not as many scientific opportunities exist as we would hope.

At the level of basic research, the eventual application of findings to a particular disease cannot be foreseen, yet it is precisely through our funding of fundamental research that advances have been made in several important rare diseases.

For example, significant advances have been made in the past 3 to 5 years in the understanding and treatment of myasthenia gravis. While the etiology of this disorder is not yet fully known, studies in fish have helped scientists to elucidate the way in which nerves tell the muscles to contract. These findings, coupled with new information on basic immunology, have allowed scientists/physicians to develop hypotheses which are leading to a better understanding and treatment of the condition.

In the area of developing drugs to treat rare diseases, NIH is primarily involved in anticancer drugs, vaccines, anticonvulsants, and antiviral agents. In FY 1983, it is estimated that about $68 million will be allocated to developing drugs to treat rare diseases; about $48 million of that will be devoted to development of anticancer drugs.

RESEARCH EQUIPMENT AND INSTRUMENTATION

"inadequate funding of research equipment, with a rapidly growing obsolescence of scientific instrumentation . . ." (p. 11, Senate Report 97-461)

"The Committee . . . encourages HHS to examine possible solutions . . . which might aid in alleviating this significant problem" (p. 13)

Currently, the NIH research project system provides for relatively inexpensive equipment that does not lend itself to shared usage; shared instrument grants provide medium-priced instruments that

are shared on an institutional basis. For example, to meet the needs of research projects of interest to the National Institute of General Medical Sciences (NIGMS), instrumentation which can be used by a group of investigators is provided for some NIH grantees (at least half of whom must be NIGMS grantees) through a shared instrumentation program. In addition, the Division of Research Resources (DRR) provides for shared instrumentation through institutional awards to qualified grantees. In FY 1982, a total of about $5 million was allocated for shared instrumentation; expenditure of $16 million is estimated for FY 1983. The purchase of shared instrumentation is also possible under a DRR Biomedical Research Support Grant.

In addition, the DRR Biotechnology Resources Program is set up to assure development and availability of high-technology instruments so costly that they must be shared on a regional or National basis. In FY 1982, about $20.3 million was allocated for this program ($15.3 million from DRR); about $36.4 million is estimated for FY 1983 ($20.4 million from DRR).

A pilot series of co-funded program project grants (funded by DRR and the appropriate categorical institute) is now being considered by NIH as a means of fostering combined sources of support for categorical instrumentation needs.

NIH recognizes the seriousness of this problem and is looking into the most efficacious means of solving it, including consideration of the value of cost sharing with other Federal agencies or with industry.

COMPETITION FOR RESEARCH FUNDING

"increasing competition and friction among scientists and lay advocates of specific disease or organ system research programs, who seek for targeted funding, or specific legislative emphasis" (p. 11, Senate Report 97-461)

NIH is also increasingly concerned about this situation. Over the past 10 years, there have been over ten legislative proposals to establish new NIH Institutes, and numerous proposals to set aside funds or otherwise to place special emphasis on certain programs related to specific diseases or systems of the body. The unfortunate consequence of these mandates is to limit increasingly the ability of NIH to support a broad range of research projects directed not at narrow and isolated components of public health, but at the whole spectrum of activities designed to understand, prevent, and treat disease.

Legislation recently introduced in the House (H.R. 2350) exemplifies this problem by requiring specific earmarks of funds or special emphasis or activities for:

Health Promotion and Disease Prevention Centers;
Cancer Centers;
Kidney and urologic diseases research centers;
Research in spinal cord regeneration;
Operation of the National Center for Health Care Technology;
Sickle cell disease centers;
Pertussis vaccine study;

Study of personnel for health needs of the elderly;
Study of commercial use of biomedical research results;
Interagency committee on learning disabilities;
Research into diet therapy in the treatment of end-stage renal disease;
Research in the relationship between diet and cancer;
Research in developing research methods that reduce the use of animals or minimize animal pain;
Mental retardation centers; and
National Commission on Orphan Diseases.

COORDINATION OF RESEARCH AMONG FEDERAL AGENCIES

"ineffective coordination and cooperation among some Institutes at NIH and other federal Agencies conducting related health research projects" (p. 11, Senate Report 97-461)

The NIH has developed a variety of mechanisms for achieving coordination of biomedical research activities and promoting effective collaboration. For example:

Disease prevention has been identified as a major Departmental initiative, and the NIH has assumed an active role in implementing this initiative by establishing a position of Special Assistant to the Director, NIH, for Research Related to Disease Prevention to work with the NIH Institute Directors in developing a coordinated program. To assist in this program, a trans-NIH committee was established to provide a strong link between the Office of the Director, NIH, and the Institutes in identifying and coordinating opportunities in disease prevention and relating the NIH effort to the overall Department initiative.

In response to growing concerns about the health effects of chemical agents in the environment, the Secretary, DHHS, established the National Toxicology Program (NTP) to: (1) integrate DHHS activities to permit the most effective use of resources, (2) consolidate existing expertise, and (3) establish a dialogue between the research and regulatory agencies. The activities of the NTP are planned and conducted under the leadership of a Program Director who is also Director of the National Institute of Environmental Health Sciences. In addition to the relevant PHS agencies and regulatory organizations, various industry associations, public interest groups, and members of the scientific community actively participate through membership on a Board of Scientific Counselors, through public peer review of Technical Reports and an Annual Plan, and through attendance at public meetings.

The Interagency Radiation Research Committee was established in response to legislation (P.L. 95-622) directing HHS to "establish a comprehensive program of research into the biological effects of low-level ionizing radiation" and "conduct a comprehensive review" of Federal research programs on the biological effects of ionizing radiation. It was the intent of Congress that this review also coincide with the development of a comprehensive Federal strategy for future research in this area.

Many of the NIH Institutes have assumed primary leadership responsibility for coordinating activities in agency-wide areas of research. Through such mechanisms as, for example, the Diabetes Mellitus Interagency Coordinating Committee, the Arthritis Interagency Coordinating Committee, and the Cystic Fibrosis Coordinating Committee, the research, research training, data collection, and information transfer activities of the agencies are dealt with in a coordinated fashion.

Within the NIH a wide variety of trans-NIH coordinating committees have been established to identify areas of mutual interest, to develop joint program announcements, and to share in the development of workshops, conferences, and symposia designed to identify areas of research need and to stimulate research in areas of highest priority. One highly successful example of this is the NIH Nutrition Coordinating Committee.

In addition, NIH Institutes are involved in many informal collaborative activities and participate in many interagency agreements designed to facilitate biomedical research.

NATIONAL INSTITUTE ON AGING

"Transfer of the Laboratory of Neurosciences to . . . Bethesda" (p. 12, Senate Report 97-461)

In FY 1982 the Institute's Laboratory of Neuroscience established a clinical research program at the Warren G. Magnuson Clinical Center at NIH, with use of a sick bed patient care unit. The basic research program of the laboratory will be relocated from the Gerontology Research Center in Baltimore to the Clinical Center at NIH this coming summer. Location of the total program at NIH will greatly facilitate our overall research collaborative efforts with the intramural program of the other institutes. This laboratory will examine changes in the normal brain with age and the dementias, and such areas as cerebral metabolic changes. For example, glucose metabolism is one of three major interrelated measures of brain activity—the other two being brain blood flow and oxygen consumption. NIA investigators have found no significant age—related alternations in brain glucose metabolism. These studies suggest that the healthy aged brain is as active and efficient as the healthy young brain. Future studies will continue to build upon and analyze the results of this work, and will lay the groundwork for research on various pharmaceutical approaches in the treatment of the dementias.

Aplastic anemias and Fanconi's anemia (Page 17, Senate Report 97-461)

Aplastic anemia is most commonly acquired but there are patients with a genetic predisposition to bone marrow failure who are said to have "constitutional" aplastic anemia. Fanconi's anema is perhaps the most commonly reported congenital aplastic anemia. There have been slightly more than 300 cases cited in the literature and new cases are being added to the list as a result of a recently inaugurated International Registry, located at the Rockefeller Institute. In contrast, almost 3,000 deaths per year are due directly or indirectly to acquired forms of aplastic anemia.

Patients with Fanconi's anema are born with characteristic organ and bone abnormalities. The inheritance pattern is autosomal recessive and the gene frequency of the heterozygote is calculated to be approximately 1/300. An interaction of the Fanconi's anemia gene with the environment has been suggested by reports of the simultaneous onset of aplastic anemia following a viral illness.

Most patients die before the age of 25 and only 50% survive for 5 or more years after diagnosis. Andorgens are helpful in about half the cases, and they prolong life by as much as 5 years. Bone marrow transplantation, if done early, may hold promise for future treatment. However, results to date have been disappointing, in part, it is believed, because of the use of cytoxan to prepare the patient. This agent apparently leads to bone marrow damage which compromises the transplant. New approaches to transplantation, however, appear to be more promising.

Several Institutes at the NIH provide extensive support for normal hematopoiesis research but, in light of recent scientific advances, more research directly related to aplastic anemia would be desirable. In an effort to stimulate and support more research in this important area, the Division of Blood Diseases and Resources issued a Request for Applications (RFA) entitled, "Etiology, Pathogenesis, and Treatment of Aplastic Anemia." Fanconi's anemia is specifically highlighted in this announcement. We have received 45 letters of intent to submit a proposal for the April 15, 1983, receipt date. We anticipate making about five awards on September 30, 1983.

In addition to this RFA, the NHLBI has organized an international conference on aplastic anemia which will be held June 26–28, 1983, at Airlie House in Virginia. The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, the Fogarty International Center, and the University of Washington will cosponsor this meeting which is intented to bring together clinicians and basis scientists to discuss recent laboratory and clinic advances related to aplastic anemia.

Coordination of hematologic research within the NIH. (Pages 16, and 17, Senate Report 97–461)

Hematologic research at the NIH is distributed among a number of Institutes, but is largely focused in the National Heart, Lung, and Blood Institute, the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, and the National Cancer Institute. Research programs of these three Institutes are well coordinated and the red cell and bone marrow interests of NHLBI and NIADDK complement each other.

Hematologic research at the NIH is coordinated through several committees which provide formal channels for communication. Through this mechanism, overlapping programs are avoided and activities which might fall "through the cracks" are reviewed.

The committees are as follows:

(A) Intra-NIH coordinating committee for blood-related activities

The function of the Committee is to serve as a principal mechanism for coordinating and integrating blood and blood-related research programs conducted or supported by the NIH.

The membership of the NIH Coordinating Committee for Blood-Related Activities represents eight major components of the NIH. NHLBI is the lead agency for this Committee and the Director, Division of Blood Diseases and Resources, has been delegated the chairmanship by the Director, NHLBI.

(B) Interagency technical committee (IATC)—Working group on blood resources

The goal of the IATC Working Group on Blood Resources is to examine and coordinate Federal research activities which concern blood and its substitutes, which are designed to reduce disability, morbidity, and mortality from diseases or conditions for which whole blood, its components or substitutes, provide preventive or curative treatment.

Memberships include most Federal agencies with programmatic interests in blood resources. In additions, representatives of a number of professional societies, blood bank associations, and health foundations are invited to participate in these meetings.

(C) Sickle cell disease advisory committee

This Committee was established by the Secretary of HEW on May 9, 1971, to advise the Secretary on the Sickle Cell Program, to suggest priorities within the Program, and to make recommendations on matters pertaining to planning, implementing, and evaluating various aspects of sickle cell disease. The Committee reviews activities across Federal agencies to avoid unnecessary overlap.

Membership consists of seven health care delivery representatives, four prominent lay leaders, and a number of ex officio members.

Finally, grant referral guidelines published and periodically revised by the NIH Division of Research Grants help to ensure appropriate assignment of hemotologic research grant applications to relevant NIH institutes.

Coordination of lung research within the NIH and other government agencies. (Page 17, Senate Report 97-461)

The Interagency Technical Committee (IATC) coordinates those aspects of all Federal Health programs and activities relating to heart, blood vessel, lung, and blood diseases and blood resources to assure the adequacy and technical soundness of such programs and to provide for the full communication and exchange of information necessary to maintain adequate coordination of such programs and activities.

The IATC, which is comprised of seventeen Federal agencies, including the National Heart, Lung, and Blood Institute, meets at least twice a year. In 1982, the IATC devoted its September meeting to discussions on research in pulmonary diseases. Two major scientific presentations were made to the Committee. Dr. Carol Vreim, Chief of the Interstitial Lung Diseases Branch, Division of Lung Diseases, NHLBI spoke on the syndrome known as primary

pulmonary hypertension and described current research efforts and the Division's recently initiated patient registry designed to collect and evaluate data on patients with the syndrome.

Dr. Thomas Hodous of the National Institute on Occupational Safety and Health (NIOSH) described the pulmonary disease research program supported by the NIOSH and discussed in detail current understandings and research activity on occupational lung diseases including byssinosis, coal miners pheumoconiosis, and chronic bronchitis among cement workers.

The IATC also makes available to its members current listings of federally-sponsored research projects in heart, blood vessel, lung, and blood diseases and blood resources. These listings have encouraged interagency cooperation and coordination.

Recently, the NIH Director also announced that the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) will have lead responsibility for coordinating cystic fibrosis (CF) research at NIH. Co-chairing the NIH CF Coordinating Committee are representatives from NIADDK and NHLBI.

No additional administrative costs were engendered for these efforts.

NUTRITION RESEARCH

"Nutrition may play a pivotal role in the development of many diseases, including our most debilitating and costly chronic diseases, and the Committee feels it is in the best interest of our citizens to encourage all institutes to emphasize and enhance nutrition-related research relevant to the respective disciplines. One noteworthy example of much needed research relates to nutritional therapy of patients with chronic renal disease. Previous studies suggest renal failure can be substantially retarded by such treatment, and if implemented on a large scale could result in considerable savings to the Federal End Stage Renal Program." (Senate Report No. 97-461, p. 12)

The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases shares the Committee's interest in nutrition research, as it relates to kidney disease. In Fiscal Year 1982, the Institute supported about $4 million in research related to the broad area of nutrition and kidney disease. In April of 1982, we supported a conference on nutritional therapy and chronic renal disease. The Institute has also supported pilot studies to determine patient compliance with low protein diets, and has directed approximately $7 million to a 6-year national cooperative dialysis study, which included assessment of nutritional parameters. Most recently the institute has developed two new initiatives, which it plans to begin in Fiscal Year 1984. These initiatives will involve studies of (1) the natural history and progression of the diseases leading to end stage renal disease and (2) identifying quantitative indices for initiating dialysis. Investigation of nutritional variables will be an inherent and important part of both of these initiatives.

RESTRUCTURING OF NIADDK

"The Committee expects the Secretary to report back to the Committee on the effect of the NIADDK restructuring, and to

evaluate the degree to which the restructuring has addressed the perceived inequities." (Senate Report No. 97-461, p. 17)

The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) was elevated to a bureau of the National Institutes of Health in April 1982. In his report to the Committee on S. 1939, legislation introduced in the 97th Congress to create a separate institute for arthritis and musculoskeletal diseases, former Secretary Schweiker commented on the benefits of the NIADDK having achieved bureau status. Assistant Secretary for Health, Edward N. Brandt, Jr., also reported in this regard at hearings held on this bill by the Committee in July 1982.

Essentially, bureau status has helped NIADDK leadership to improve managerial effectiveness and to enhance NIADDK relationships with advisory and constituent groups. With respect to perceived inequities, bureau status has largely enabled NIADDK to begin a new budget allocation process which permits each division to participate more directly and fully in budgetary decisions and to have greater flexibility in allocating funds among its respective programs. This process is also geared toward greater consultation with concerned health voluntary and professional groups and toward making more equitable allocations among divisions. The arthritis community—the Arthritis Foundation, the National Arthritis Advisory Board, and other groups—is now participating fully in NIADDK budget discussions. The Arthritis Division has clearly benefited from this new approach, and was the only NIADDK component which did not absorb a portion of the $1 million loss NIADDK incurred in Fiscal Year 1982.

Other advantages of bureau status are:

Increased public visibility for the Department's national research effort in arthritis, diabetes, digestive diseases and kidney diseases.

Establishment of a more effective organizational structure for improved management of these high-priority national programs.

More highly focused responsibility for the national research efforts in arthritis, diabetes, digestive diseases and kidney diseases, and other specialized areas.

COORDINATION OF SKIN RESEARCH

"A need (exists) to coordinate research conducted in skin diseases throughout the National Institutes of Health, as well as the National Institute for Occupational Safety and Health." (Senate Report No. 97-461, p. 18)

Coordination of skin diseases efforts at NIH and throughout the Federal Government is being enhanced through an ad hoc interagency dermatology working group. To date, this group has met three times, and a fourth meeting is planned during 1983. The chairman of the group is the Skin Diseases Program Director, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK). The working group includes representatives from the National Institute of General Medical Sciences; the National Heart & Lung, and Blood Institute; the National Institute of Allergy and Infectious Diseases; the National Cancer Institute; the

National Institute on Aging; the National Eye Institute; the National Institute of Neurological and Communicative Disorders and Stroke; the National Institute of Environmental Health Sciences; the National Institute of Dental Research; the Division of Research Resources; the HHS Division of Nursing; the Food and Drug Administration; the Veterans Administration; and the National Institute of Occupational Safety and Health. Objectives of the working group include:

To provide up-to-date information on funded research projects within the various institutes and agencies.

Identify gaps in under-supported areas of research within the field of skin disease related problems.

Identify common interests within the area of skin-disease related research; that is, areas of interest to more than one institute or agency.

Coordinate Federal activities in skin disease related research.

Aid in the proper assignment and referral of applicants and applications related to skin diseases.

Aid in the search for funding of important projects.

Stimulate new research and research initiatives within skin diseases.

Develop reasonable, accurate financial estimates for the support of skin-disease related research and in particular for some of the subgroups within that broad category.

The working group has been guided in its work by the 1979 NIADDK-supported evaluation study, "Analysis of Priorities and Needs for Research in Dermatology." As requested by the House and Senate Appropriations Committees, the Institute is currently in the process of updating this analysis, and expects to have a revision available at the appropriations hearings on the Fiscal Year 1985 budget.

DIGESTIVE DISEASE EPIDEMIOLOGICAL DATA

"The Commitee has heard of considerable concerns expressed by the digestive diseases research community regarding inadequate epidemiological data. Insufficient attention to such research related to digestive diseases is unfortunate in view of the prevalence and disability associated with these illnesses." (Senate Report No. 97-461, p. 18)

The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) recognizes and shares the Committee's concern regarding the need for epidemiologic data in digestive diseases research. Currently, the Institute is developing a proposal for a digestive diseases epidemoiology and data system program. This proposal is being formulated by a gastroenterologist and data system expert from Johns Hopkins University, who is in consultation with other experts in the field. It is expected that the NIADDK program will pursue cooperative epidemiology initiatives with other organizations. The Institute is already working with the National Center for Health Statistics (NCHS) on a project to determine the prevalence of gallstone disease in subjects participating in an NCHS study of Hispanic Americans. In addition, efforts will be

made to employ data obtained from endoscopic studies as a model of a data system in archive. This project will be pursued this summer under the aegis of the American Society for Gastrointestinal Endoscopy.

The Institute has also promoted a workshop which considered diagnostic criteria for functional bowel disease. Studies to arrive at precise definitions for this condition are under way. Interested investigators are applying the criteria developed at the workshop under field conditions in order to arrive at a practical and standard basis for diagnosis.

The Institute recently issued a solicitation for exploratory grants for digestive diseases research centers. These centers will provide unique opportunity to gather epidemiologic data and to study populations with digestive diseases. Institutions having an interest in expertise in the epidemiology of digestive diseases are able to submit applications under this announcement. The Institute welcomes and encourages work in epidemiology and recognizes that this field needs nurturing.

DIGESTIVE DISEASES RESEARCH CENTERS

"Advocates for patients suffering from digestive disorders, as well as the research community, have recommended establishing research centers similar to those which have proven successful in facilitating research in other specific health problems, i.e., cancer centers, arthritis centers. . . . The Committee recommends NIADDK consider development of such centers supporting digestive diseases research as recommended by the Digestive Diseases Advisory Board, with consideration of resources available and continuation of funding the recommended level of research grants." (Senate Report No. 97-461, p. 18)

Recognizing the interest of the Congress, the research community, and the Digestive Diseases Advisory Board in the establishment of digestive diseases research centers, the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK), published a solicitation for exploratory grants for such centers in February 1983. The solicitation is provided for the record.

The objective of the exploratory grant is to provide partial funding for the cost of planning and developing a high quality digestive diseases center. The special receipt date for submission of applications is May 16, 1983, with the earliest funding date being September 26, 1983. Successful exploratory grant applications will be funded in amounts not to exceed $25,000 in direct costs for a 12-month period.

The digestive diseases centers will be charged to develop and conduct basic and clinical research into the cause, diagnosis, early detection, prevention, control and treatment of digestive diseases and related physiological, pathophysiological, congenital or metabolic disorders resulting from such diseases. The planning phase of the grant may consist of but is not limited to:

Departmental and interdepartmental planning to integrate a broad spectrum of digestive disease related activity;

Planning the establishment of specialized resources and facilities;

Feasibility surveys to identify appropriate patient populations, identify special problems and opportunities, etc.

Use of consultants to solidify plans for center activities and resources.

The NIADDK expects this initiative to enhance research efforts in digestive diseases, and is pleased to respond administratively to Congressional interest in this area.

CONTINUING CARE OF THE CANCER PATIENT

"Sections 401 and 403 were amended to require research be conducted related to continuing care of the cancer patient and the family of the cancer patient. This addresses the concern that a number of cancer victims suffer tremendous psychological, economic and social problems related to their illness." (page 14, Report No. 97-461)

The National Cancer Institute (NCI) agrees that this is an important and often overlooked area of research, therefore last year the NCI hired two individuals with specialized experience in the area of continuing care.

In May, 1982 the Institute hired Dr. Jerome Yates who was serving at the time as the Associate Director for Cancer Control of the Vermont Regional Cancer Center. Dr. Yates has extensive experience in the areas of costs related to cancer care, pain control, education of community nurses and physicians who care for cancer patients, and general outreach activities. We are in the process of evaluating the impact of the NCI's previous continuing care research efforts, and we anticipate new initiatives being developed in the areas of economic impact of cancer, psychosocial support systems for the patient and the family, pain management, quality of life issues and physical rehabilitation. Dr. Yates also has participated in the Advisory Committee of the National Hospice Study and we will be reviewing this material as it relates to the research program at the National Cancer Institute.

Dr. Lee Gigliotti has been hired as Chief of the Education Branch. Dr. Gigliotti is a nurse-educator who has been brought to the NCI to develop professional education activities with an emphasis on pain management and continuing care.

SUPPORT OF CANCER CENTERS

"The dollars devoted to cancer centers have increased over the past several years, but the proportion of the total budget devoted to cancer center support has gradually fallen. The Committee urges the NCI leadership to review this trend and maintain support for cancer centers at a level which will ensure their stability." (page 14, Report No. 97-461)

The National Cancer Institute (NCI) has reviewed the allocation of the NCI budget dollars to cancer centers and has demonstrated that the proportion of NCI budget dollars devoted to core grants for centers has risen steadily since 1977. Actually, centers have received a greater portion of the total NCI budget virtually every year since 1977. Moreover, the dollars allocated to centers have increased even though the total NCI budget decreased in 1981 and 1982.

The Institute believes that cancer centers are essential to the progress we are making in cancer prevention, research and treatment. We have said on numerous occasions that the NCI is committed to this program, and we will do our absolute best to see that they receive the resources they need to continue their important work.

MEMBERSHIP OF NATIONAL CANCER ADVISORY BOARD

"The legislative authority for the National Cancer Advisory Board was left intact. Nonetheless, the Committee is concerned that individuals considered to fill vacancies should include those knowledgeable in environmental carcinogenesis." (page 15, Report No. 97-461)

Ten of the 18-member National Cancer Advisory Board (NCAB) have indicated an interest in environmental carcinogenesis. Of these 10, five are individuals that have scientific expertise in the area. It may be worth noting that appointments to the NCAB are made by the President, who receives nominations from a variety of sectors of the Government, including the National Cancer Institute, and the private sector.

ORGAN SITE PROGRAM

"The National Cancer Advisory Board has made approximately eleven reviews of the Organ Site Program over the last decade, all of which have supported continuation of organ site programming. . . . The Committee expects continued funding for these important programs and establishment of the recommended new task forces, as resources permit." (page 15, Report No. 97-461)

The Committee is correct in its citation of the numerous reviews that have been done of the Organ Site Program. The most important of these reviews is the one commissioned by the National Cancer Advisory Board (NCAB) in the fall of 1981. For the first time an independent body of scientists reviewed the program. These scientists noted several areas that needed restructuring, most notably the need to separate review from program. Early in 1982 the NCAB Subcommittee on the Organ Site Program, after discussing the results of the independent review, developed a set of recommendations for change that were passed unanimously by the full NCAB at its May 1982 meeting. Major components of these recommendations included the separation of reveiw and program by bringing the review function into the normal NIH/NCI review system—including the establishment of special study sections as needed, establishment of one external coordinating center, continued emphasis on the genitourniary/gastrointestinal systems, use of existing NCI mechanisms for clinical trials research, and renaming of the program as the Organ Systems Program.

During the fall of 1982 the Organ Systems Subcommittee of the NCAB expressed an interest in reviewing the NCI implementation plans of the NCAB May recommendations, with a view to elaborating upon these recommendations. With the exception of the establishment of a single coordinating center, the Board's recommendations had been implemented. Accordingly, the NCI agreed to delay the issuance of the Request for Application (RFA) for the external

headquarter's offices until such time as the Subcommittee could reconsider its recommendations. The funding of the existing four Organ Site Program headquarters was extended.

In late January 1983 the Organ Systems Subcommittee met for one and one-half days to review the restructuring of the Organ Site Program. With some modifications, the Subcommittee developed a set of recommendations consistent with the May 1982 NCAB recommendations, and after consideration and further modification, the full NCAB unanimously adopted the Subcommittee's organ systems recommendations.

The RFA establishing the external coordinating headquarters was issued in March 1983. An award is anticipated at the end of FY 1983.

The NCI has no plans to dismantle research related to specific organ sites; rather the Institute is restructuring and modernizing the program in order to increase its flexibility in dealing with areas that may need more attention and to make it more cost effective. It is thought that by following the recommendations of the NCAB, the deficiencies in the current administrative structure can be rectified and that organ site research will compete with all other significant research that is supported by the Institute.

CANCER EDUCATION PROGRAMS

"The Committee expects the NCI will continue funding cancer education programs. However, the Committee is concerned whether NCI should continue to fund a large number of post-doctoral training programs in oncology when the need for these specialists is likely to decline in view of the Graduate Medical Education National Advisory Council (GMENAC) report projections of imminent physician surplus." (page 16, Report No. 97-461)

Only a few years ago a cadre of cancer specialists did not exist in this country. National Cancer Institute (NCI) training programs in research and clinical medicine have seeded the country with cancer specialists. The Institute agrees that it is important to coordinate our training efforts with national trends and we are doing so. About a year ago we revised our training guidelines and established the Professional Oncology Training Program. This program is not limited to medical and dental schools and their affiliated hospitals. Rather, training opportunities are available for all health professionals, including undergraduate students. The goal of this program is to integrate the teaching of cancer epidemiology, prevention, nutrition, and cancer control with clinical and basic science in the management of cancer.

Of the 154 NRSA individual fellowships awarded by the NCI in FY 1982, only seven were awarded to physicians.

In general, the Committee is pleased with the prompt response to concerns conveyed in Senate Report 97-461. It is apparent that in most respects appropriate and effective action has been taken or is soon to be implemented. However, the following represent some of the persistant concerns of the Committee related to problems cited in Senate Report 97-461, and requests for further information, or efforts for resolution:

FRAUD AND ABUSE

The Committee is pleased with the establishment of a Public Health Service task force charged with making recommendations on how fraud and mismanagement of NIH funds can be diminished. It is apparent that recommendations from the preliminary work of this task force have identified common concerns to Congress and, if implemented, will diminish future opportunities for mismanagement and fraud. However, the Committee is concerned whether since June 1981 there have been investigations of research scientists, appropriate reprimands, and research funding withheld when mismanagement has been detected. The Committee is anxious that the work of the task force, and the requests of Congress not be ignored by officials at NIH and that the goals are eventually achieved.

PEER REVIEW

The Administration's report on the peer review system is welcome and appreciated. Clearly, the peer review system is preferred to alternatives, but given the opportunity for "some inequities", it is essential that there be a forum for redress. Also, it is hoped that young and accomplished research scientists will continue to be integrated into the peer review panels.

INDIRECT COSTS

Indirect costs continue to be a source of major concern for the Committee. Representatives of research universities, research scientists, and professional organizations have united in opposing broad, across the board cuts in indirect costs. The proposal from the Administration for fiscal year 1984 would translate into approximately a 10 percent reduction in indirect costs, the same proposal as the previous fiscal year, and the Committee has ample evidence that this would result in significant hardships and eventually a diminished research effort at many of our research universities. Included herewith is a summary of the views of the Association of American Universities (AAU), American Council on Education (ACE) and the National Association of State Universities and Land-Grant Colleges (NASULGC). Although the Committee does not endorse every concern and recommendation of this statement, it deems the concerns expressed important and worthy of thorough consideration before there are major changes in policy related to indirect cost reimbursement.

On February 17, 1983, representatives of the Association of American Universities, the American Council on Education, and the National Association of State Universities and Land-Grant Colleges attended a meeting with other representatives of the higher education and biomedical research community and officials of the Public Health Service on the subject of indirect costs. Following this meeting, the university associations were invited to submit comments for the record to be forwarded to Office of Management and Budget (OMB) for inclusion in the Public Health Service's response to the request of the House Appropriations Committee. The

following is a summation of our views as presented at the meeting on February 17th.

INTRODUCTION

The Nation's biomedical research effort will be vitally important in the next five years. It will attract a great deal of attention from the public and from the Congress. The central items about which the Congress is likely to express concern are:

Whether the research is sufficient for our nation's need,

Whether it is of high enough quality and,

Whether it is appropriately connected to, on the one hand, the productive sector of the economy which helps us to compete in world wide markets and, on the other, the practitioners who work to improve the health of the American people.

Our success in being able to fulfill our responsibilities will depend on strong academic institutions working in cooperation with a strong NIH for the purpose of supporting optimally those who do the real work, that is, the principal investigators and their research colleagues.

This relationship can be strained by continued disagreements over appropriate apportionment of research funds. Care must be taken to avoid such strain; equitable and mutually agreed upon resolution must be pursued by both the university research community and the Public Health Service.

It is well to remember that the Congressional mandate for a review of the issues surrounding indirect cost is:

> "The Committee is persuaded that indirect costs are a legitimate component of the costs incurred in performing biomedical research and should be adequately reimbursed. The Committee is also concerned by the widespread perception that federally sponsored research may be bearing more than its fair share of these costs . . . The Committee requests the Secretary of Health and Human Services, in cooperation with the NIH Director, to make a careful review of this matter, including consultation with the universities and other research organizations most directly affected and to submit a report setting forth conclusions and appropriate recommendations . . ."

We who represent the heads of the institutions where most of the research is carried out believe that NIH has assumed wrongly that indirect costs of research have been rising faster than they should. The word "disproportionately" has been used and NIH has set about trying to rectify this wrongly perceived problem. We believe that research costs are the issue. Our job is better to understand the costs of research and the proper apportionment of these costs. We do not believe that indirect costs are rising disproportionately. On the contrary, we believe that moneys for direct costs are not rising fast enough to meet the costs of inflation. We suspect that the deflator used by the NIH to express expenditures in constant dollars is too low. We take as evidence for this assumption the fact that the percent of the budget allocated to indirect costs has been rising.

It is not possible to decide this issue in time for this year's Congressional hearings. It is not right to budget decreased indirect

cost reimbursement before Congressionally mandated consultation has taken place. It would be wrong to abrogate unilaterally the agreed upon principles of OMB Circular A-21.

As the Committee notes, indirect costs of research are legitimate research costs. We join the Committee in concern over the widespread perception that the federal government is bearing more than its share of these costs: it is this set of perceptions that we believe need careful study. We are aware of the rise in the rate of indirect costs and believe much, if not all of this increase can be explained and justified as legitimate costs of research. We are eager to join in efforts to explore further this increase, especially if such efforts can yield fruitful ways to control indirect cost expenditures.

At the invitation of Drs. Brandt and Wyngaarden we have joined in the beginning of what we hope will be continuing discussions of this issue. We appreciate being consulted by the National Institutes of Health and the Public Health Service as they seek answers to the complex set of questions about indirect costs and the appropriate federal investment in support of biomedical research. We have appended our response to the invitation from the PHS to discuss these matters.

FACTORS CONTRIBUTING TO THE PERCEPTION THAT THE FEDERAL GOVERNMENT IS PAYING MORE THAN ITS SHARE OF INDIRECT COSTS AND/OR THAT SUCH COSTS HAVE RISEN DISPROPORTIONATELY:

(1) There is little awareness that both direct and indirect costs are essential to the performance of research. Direct costs are highly visible, while indirect costs are pooled costs that are not easily identifiable to an individual research project.

(2) There are those who believe that indirect costs are reimbursed without review: Indirect costs are subject to the careful scrutiny, review, and approval or disapproval by federal auditors; such costs are allocated to cost pools by the institution and reimbursed by the federal government in accordance with federal guidelines.

(3) There is failure to appreciate the indirect costs are truly research costs, and that without reimbursement for these costs the universities would be substantially weaker hosts to the nation's biomedical research: Research costs are divided between the direct and indirect categories only because there are some institution-wide expenditures incurred on behalf of all research activities that are charged as indirect costs for convenience and accounting purposes.

(4) There are those who believe that indirect costs are general institutional funds, or that they support non-research activities such as teaching: Indirect costs at universities are divided into cost pools; teaching costs and other non-research costs are segregated from the cost pool designated for sponsored research.

(5) There are those who believe that universities are reimbursed fully for direct and indirect costs of research: In fact, current federal cost principles are based upon mandatory university contribution to research costs.

(6) There is a belief that universities do not have adequate incentives to control indirect cost expenditures since they are reimbursed by the federal government: The facts are, all indirect costs are shared between universities and the federal agencies that sponsor research; universities pay more than ½ of each dollar in the indirect cost category. Savings of this magnitude is more than adequate incentive to control costs.

(7) The belief that indirect costs have risen disproportionately seems to be based upon the change in the average rate in the past ten years. There are a number of readily apparent reasons for this proportional increase:

Direct costs of research have not kept pace with the cost of conducting research;

Items in the indirect cost category (such as energy costs) have risen disproportionately;

Prior to 1966, indirect costs were capped;

Better management and improved identification of costs demanded by both the universities and the government has revealed that more costs must be appropriately allocated to research than earlier believed;

The nature of biomedical research has changed: there is more equipment sharing, larger and more complex research teams, and therefore more pooled costs attributable to indirect cost categories.

NEXT STEPS

Congress has asked the DHHS to explore the perception that the federal government is paying more than its share of indirect costs. We believe it is vitally important to the nation's biomedical research enterprise and to the relationship between the research agencies and the universities to take this charge seriously, to explore these perceptions, and to reach conclusions in as timely a fashion as possible.

We believe there exists a set of questions in need of answers in order to deal responsibly and effectively with the perceptions about which the Committee has expressed concern:

(1) Are there currently allowable costs, that should be excluded from federal reimbursement? If so, on what basis should they be excluded?

(2) Are there economies and efficiencies which could be introduced, and at what cost to research productivity and/or accountability?

(3) What are the principles that guide decisions about proportional share (as established first in 1947 and reiterated by Congress in 1976, these principles are: federally sponsored research shall leave the institution with no gain and no loss)? Should these principles change?

(4) How do other performers, such as industry, deal with the reimbursement of indirect costs? Should universities be treated differently?

(5) What are the cost factors involved in the increase in indirect cost rates?

We believe that the past few years have witnessed growing attempts to cut reimbursement of the direct and indirect costs of research. It is not possible to buy the same amount nor the same quality of research for less money. In fact there is good reason to believe that the total cost (direct and indirect) of top quality, cutting edge research, has gone up significantly for a wide variety of reasons. To ignore this increased cost is to harm the research effort, compromise the next generation of scholars, and erode this nation's leadership in biomedical research.

The existing government-wide policy of OMB Circular A-21 sets forth a process, and criteria for applicability, allow-ability, and cost analysis. We believe it is essential to understand the principles underlying A-21 before reaching any conclusion about indirect costs.

The nature of indirect costs has long been a controversial subject. We appeal to the Administration and the Congress to aid the community in establishing a coherent and logical process to seek resolution of differing views and to find whatever solutions make sense once perceptions can be refinded into fact. We believe that perceptions are substantiated more by the lack of good answers to critical questions than by the existence of any data.

PREVENTIVE MEDICINE

The Committee is also pleased to learn of increased allocation of resources and effort in preventive medicine research. Nevertheless, on balance, the Committee feels that there is still insufficient research in preventive medicine and health promotion. Consequently, a separate bill, S. 771, the Preventive Medicine Research and Health Promotion Act of 1983 was introduced which would establish in statute an Assistant Director of Prevention at NIH and require an annual report related to all preventive medicine research activities. Furthermore, the Secretary of HHS will be required to fund centers for research in preventive medicine and health promotion at academic health centers. It is hoped that if this legislation becomes law that the research from such centers will provide data which will be complementary and facilitate expansion of relevent research within the National Institutes of Health.

EQUIPMENT AND INSTRUMENTATION

The committee maintains its concern about obsolete instrumentation. Out of date instruments pose serious problems to many research centers who have been unable to keep pace with the costs of new technology. Inadequate instruments handicap many research efforts and the committee encourages implementing as soon as possible the proposed co-funded project grants (Division of Research Resources and the appropriate categorical institutes). It is hoped that this will foster improved support for funding new instruments necessary for research. It is also the hope of the committee that further efforts will be explored to encourage industry to join in cooperative efforts with funding research needs.

NUTRITION RESEARCH

There has been a considerable increase in funding nutrition research related to prevention and treatment of disease. Given the diversity of nutrition research supported by each of the eleven institutes at NIH, the Committee recommends consideration of establishing an Assistant Director of Prevention at NIH. This may facilitate improved coordination and encouragement of nutrition research throughout NIH.

ALZHEIMER'S RESEARCH

The Committee is pleased to learn of the transfer of the National Institute of Aging Laboratory of Neurosciences to the Bethesda campus. There is a strong consensus that there is insufficient research in the basic science of dementia and this was highlighted by an amendment to this legislation. Given the prevalance of dementia among our elderly citizens, and the costs of providing for their long-term care, it is hoped that an ongoing major effort will be devoted to identifying preventive measures, and hopefully cures to all forms of dementia.

CHANGES IN S. 773 FROM S. 2311

In considering S. 773, as last year when considering S. 2311, the Committee chose *not* to deal with most problems and concerns by legislative mandate. The Committee considers S. 773 a relatively straight-forward reauthorization of the NCI, NHLBI, the National Library of Medicine, and the National Research Service Awards, with authorization levels sufficient to maintain the current research effort.

The Committee has resisted multiple attempts at targeting funds on disease specific research, recognizing that previously NIH has been responsive to public concerns conveyed by Congress. Nonetheless, ongoing oversight is deemed essential. Oversight hearings have been held in the past and will continue to be scheduled to highlight areas of concern and provide NIH with the necessary Congressional leadership to provide the most efficient and effective use of federal dollars devoted to the biomedical research effort. It is the hope of the Committee that his consultation between the Congress and NIH will solve the growing number of problems related to this large federally funded program and will be more effective than extensive statutory changes which may prove overly rigid. This will require ongoing cooperation between NIH and the Committee. If the desired results are not apparent by the next reauthorization cycle three years hence, the Committee may need to consider significant changes in Titles III and IV of the Public Health Service Act in order to guarantee economy and progress in the research effort.

JUSTIFICATION FOR S. 773 CHANGES IN EXISTING PHS STATUTE—NATIONAL INSTITUTE FOR ARTHRITIS, MUSCULOSKELETAL AND SKIN DISEASES

The only major change is establishment of a National Institute of Arthritis, Musculoskeletal and Skin Diseases from the NIADDK.

Full committee hearings related to this proposal were held on July 20, 1982, and further testimony related to this was heard when the Committee held hearings on S. 773 on March 17, 1983. The creation of this institute is supported by the committee, given that the multiple diseases encompassed by this proposed research institute are the most common and some of the most painful of human ailments. These disorders afflict every citizen at sometime during their lives and collectively they are among the most costly.

However, the Committee is aware that two new Institutes are being created out of one existing Institute and that the administrative and related costs of establishing each of the new Institutes is likely to exceed the share of administrative costs each division of the existing Institute currently bears. The Administrative costs of operating the new NIDDKD will exceed the cost of operating the current divisions associated with it, and may approximate the cost of operating the current NIADDKD since most of the general administrative structure of NIADDKD may be necessary to operate the new Institute. Yet a separate administrative structure must be established for the new Arthritis Institute, and similarly its costs will exceed the current share of administrative costs associated with the Arthritis Division.

Relative to other NIH Institutes, NIADDKD has a lean administrative structure to begin with and at its present funding level does not have the necessary administrative funding to support the creation of two new Institutes. The Committee does not wish to see research funds used to meet additional overhead and administrative costs of either new Institute and recommends that a special appropriation item be requested by NIH at the appropriate time and made available for the additional administrative costs of each new Institute. The Committee expects that NIH will report to it and the House Energy & Commerce Committee shortly after the enactment of this legislation indicating what the administrative costs of establishing each new Institute are, what the timetable is, what administrative funds currently exist to meet those costs, and how, if needed, additional funds will be obtained to establish the new Institutes without using research program funds.

ANIMAL WELFARE RESEARCH STUDY ACT (S. 964)

S. 964 was added to S. 773, and is designed to provide a comprehensive assessment of the current status of the use of live animals in biomedical and behavioral research. The need for such a study has been brought to the attention of Congress by many of our citizens who have personally, or through animal welfare organizations expressed serious concerns about mistreatment and unnecessary killing of animals in many research programs. Many of those interested in animal welfare have encouraged laws to be enacted now which they feel would insure improved standards of animal care and humane treatment of animals used in research. The Committee is sympathetic with these goals; however, it is not certain as to the extent of animal mistreatment within the biomedical and behavioral research community, and is concerned that current proposals to upgrade federally funded animal laboratories may be unnecessary, very costly, and perhaps diminish the overall research

effort. Also, there is insufficient data regarding alternatives to current animal research which should be encouraged and promoted. Therefore, the Committee believes this comprehensive study is necessary, timely, and will provide essential information as Congress considers federal legislation regarding the use of live animals in research. Although nothing in this legislation precludes passage of other animal welfare legislation being considered by Congress, the Committee believes the data which will result from this study should be considered first.

The Committee recognizes the concerns raised by the animal welfare community and believes that its point of view should receive adequate representation on the advisory panel overseeing the conduct of the study. Accordingly, the Committee requests the Secretary of Health and Human Services to ensure a balance exists when entering into any contractual arrangement with the National Academy of Sciences or any other non-profit organization. It is the Committee's intent that representatives from the animal welfare community with scientific credentials participate in all phases of the study.

While it is not the Committee's intent to obstruct in any way the objectivity of the scientific assessment authorized by this legislation, the reliance on animal experimentation in medical research has become the center of serious public debate in this country. Resolution of such concerns shall come about only with the active collaboration of scientists who represent the full spectrum of views of the issue, and it is in this spirit that the Committee's directive is put forth. If the study data are compiled sooner than the 18 months permitted by the Act, the Committee would like to receive the results at that time.

To provide further information regarding alternatives to presently used animal research models, the Committee Chairman has requested the Office of Technology Assessment (OTA) to conduct a study related to the issue. A copy of the letter requesting study follows:

U.S. SENATE,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
Washington, D.C., March 29, 1983.

Hon. TED STEVENS,
Chairman, Technology Assessment Board,
U.S. Senate,
Washington, D.C.

DEAR TED: I am writing to request that the Office of Technology Assessment (OTA) undertake a study which would involve a scientific evaluation of alternative methods to animal research, experimentation, and testing.

An evaluation of nonanimal methods is timely. Federal and nonfederal attempts to moderate the use of animals will in turn affect biomedical research. Advocates of the animal welfare legislation claim nonanimal methods are faster, cheaper and more accurate than traditional animal experiments.

In addition to examining the use of nonanimal research methodology, I would like OTA to advise regarding what effects increased utilization of nonanimal methods might have on the total biomedi-

cal research effort. The evaluation should also consider the effect of previous legislation on animal testing.

I am particularly interested in having more information on what kinds of nonanimal research seem most promising.

I appreciate your consideration of this request.

Sincerely,

ORRIN G. HATCH, *Chairman.*

PUBLIC HEALTH EMERGENCIES RESEARCH PROVISION

The Research and Public Health Emergencies provision creates an expedited process at the National Institutes of Health for funding application for grants for research on disease or disorders that constitute a public health emergency. It is the concern of the Committee that adequate resources be available for research on diseases or disorders that constitute a public health emergency, as determined by the Secretary of the Department of Health and Human Services. Such diseases as Legionnaire's disease, toxic shock syndrome and acquired immune deficiency syndrome have been both frightening to the American public and often fatal to their victims. The recent appearance of acquired immune deficiency syndrome (AIDS) presents a public health emergency of major proportion; there is no known cure and, so far, no certain cause. It is the opinion of the Committee that necessary funds should be allocated by the Public Health service for the pursuit of AIDS research. Appearing with greater frequency among many groups as the epidemic grows, AIDS has been identified in children, Haitian immigrants, hemophiliacs, homosexual men and intravenous drug users, and more cases are appearing that do not seem to fit into any of these risk groups. Without adequate research, the pursuit of adequate treatments and cures for AIDS will be frustrated. Without adequate treatments and cures, the fears that already stalk AIDS victims and their care providers will continue to escalate.

The NIH should work with the CDC in providing information to the public and the medical community so that fears may be properly managed.

It has come to the attention of the Committee that there is great anxiety among professional, technical staff, hospital, and research staff dealing with AIDS secretions and blood specimens. Many are afraid that they do not have the training needed to handle such specimens and that they may accidently expose themselves to the unknown causative agent of AIDS. Because these fears may hinder the treatment of AIDS patients and retard the progress of AIDS research, the Committee recommends that the Division of Safety of NIH develop a training program to educate those individuals dealing with AIDS about the proper handling of secretions and blood specimens.

REPORT LANGUAGE FOR MENTAL RETARDATION RESEARCH CENTERS

The twelve Mental Retardation Research Centers constructed under Public Law 88–164 are part of a long term national program the purpose of which is, by the year 2000, to reduce the incidence of mental retardation by one half. This goal was first articulated in a Presidential Message in 1971 and has since been reaffirmed by

the President's Committee on Mental Retardation, which estimated the net cost to society for the maintenance and care of individuals with mental retardation to be 11.5 billion dollars in 1981.

Because the Mental Retardation Research Centers have been so productive in the development of methods for prevention of mental retardation and because the economic cost of mental retardation is so high, it is the strong recommendation of this Committee that NICHD continue the core grants which support these centers as long as they remain productive and maintain appropriate standards of research quality.

The core grants provide stability to the centers' operations and allow them to make a valuable contribution in meeting the Presidential goal of reducing the incidence of mental retardation. The Committee recognizes these centers as a valuable natural resource for research in mental retardation.

The Committee does not intend by its efforts to require maintenance of core support to previously approved centers which do not meet the high standards required of them. Nor does the Committee intend its language to discourage the funding of new applicants, provided their applications are peer reviewed and otherwise judged to meet appropriate scientific standards.

RESEARCH ON HEALTH EFFECTS OF NEW ENERGY TECHNOLOGIES

In the course of the Committee's work on the radiation safety and radiogenic cancer compensation issues, it learned that there is no research center devoted to the issue of radiation and health that is not directly under the control of the Federal Government. There are several national laboratories, such as Brookhaven, but there is no independent center at an independent university. Considering the central problem of credibility regarding Federal Health Research on nuclear energy, the Committee believes an indepenent center would be useful. The Committee has considerable interest in the radiation issue because of several hearings devoted to the health effects of above ground nuclear bomb testing, and has heard ongoing concern from citizens regarding the effects of underground nuclear testing and nuclear power plants. Research community scientists have advised that there would be considerable benefit in establishing an independent research center that could study the health effects and impact on local communities as new energy technologies are developed . . . for example, the effects of a large-scale effort to recover oil from oil shale. Our Nation is going to continue to need new sources of energy, and the Committee considers it essential to learn of the health effects of new energy technologies upon individuals, and the communities that host these new programs.

ALCOHOLISM, ALCOHOL ABUSE, AND DRUG ABUSE RESEARCH STUDY AT NIH

The Committee recognizes that there are excellent research activities being conducted on alcoholism and drug abuse at NIMH, NIAAA and NIDA but is interested in knowing more about related research activities that NIH is conducting. Alcoholism is the fourth

leading cause of death in our country and the Committee is concerned that NIH conduct appropriate research in this area.

PROTOCOL DATA QUERY (PDQ) AND INTERNATIONAL CANCER RESEARCH DATA BANK (ICRDB)

During consideration of the National Cancer Act in 1971, the Committee learned through contacts with scientists here and abroad, that little sharing of information on cancer research took place within this country, and that even less took place between scientists and researchers in different countries. To resolve that problem, the International Cancer Research Data Bank was established in that year. Since that time, the Committee has encouraged and promoted the growth of the ICRDB, and today its databases contain the most current information on publications, research, and treatment protocols.

Section 101(c)(1) of S. 773 strengthens the statutory foundation of the ICRDB by requiring that it and its functions be maintained and operated, and by formally recognizing its role in the promotion of treatment as well as research. This section also requires that the National Cancer Institute make its new "user-friendly" computer database system, known as Protocol Data Query-2 or PDQ-2, available to other countries through the ICRDB system. The Director of the National Cancer Institute has stated in his testimony for the Committee that PDQ-2 completes the mandate given to the National Cancer Institute in 1971 to develop new systems for referral of cancer patients to appropriate institutions and physicians and to develop and disseminate up-to-date cancer treatment information to the profession and to the general public. Distribution of PDQ-2 through the ICRDB system will strengthen the ICRDB system by making cancer treatment information available world-wide.

Section 101(c)(2) is intended to increase awareness of the PDQ and ICRDB systems. The National Cancer Institute's Director has stated that the PDQ system, by dramatically reducing the time lag between identification of new treatments and widespread national application from the minimum of five years in the past to under one year, will save a highly significant number of lives. A significant number of lives will not be saved, however, unless general practioners and researchers are aware of the Institute's information systems. In the past only the most concentrated cancer research specialists have been aware of the ICRDB, and at this time the Institute has not adopted a plan to promote and publicize the existence of the PDQ system.

Section 101(c)(2) therefore requires that the Institute publicize, as much as feasible, the availability of the PDQ and the ICRDB systems to researchers and to the doctors, both oncologists and general practioners, who see and treat cancer patients.

ALZHEIMER'S DISEASE RESEARCH

Alzheimer's disease is one of the most pervasive and devastating health problems facing the American public today, it is estimated that between 5 and 10 percent of the over 65 population suffers from Alzheimer's and related disorders. The elderly population is expected to double by early in the next century and the cost of

nursing home care alone for Alzheimer's patients is expected to reach $30 billion by the 1990s. In addition to the overwhelmingly burdensome cost of care, the disease has a devastating psychological impact on its victims and their families.

In light of these facts, the Committee determined that the present level of resources directed to research on Alzheimer's and related disorders needed to be sharply increased, particularly in the area of basic science. Therefore, the Committee has authorized an additional $4 million, over and above other funds available for biomedical research, specifically to increase the research grants directed to Alzheimer's disease. The Committee has also directed that priority be given to grants for basic science research in this area.

In addition to increased funding for research, the Committee has directed the secretary of health and human services to establish an interagency task force on Alzheimer's disease to coordinate and review the adequacy of Government programs and activities related to research on and treatment of Alzheimer's Disease, to increase awareness of the disease, and, most importantly, to develop a strategy to increase research activities related to Alzheimer's disease in order to maximize the potential for discovering the cause and thus the cure for the disease.

DIGESTIVE DISEASES RESEARCH CENTERS AND DIGESTIVE DISEASE INFORMATION CLEARINGHOUSE AND DATA SYSTEM

The Committee has heard from many professional organizations and patient advocate groups that there is insufficient research in digestive diseases. Based on previous success of disease research centers in diabetes, arthritis, and cancer, it has been the unanimous recommendation of the National Digestive Disease Advisory Board to establish similar centers in the digestive disease research. Furthermore, one of the most obvious voids in health information related to these problems is inadequate epidemiological data. It is the consensus that digestive problems are ubiquitous throughout our society, yet actual prevelence and incidence of specific disorders is simply unknown. Therefore, the information clearinghouse and data system is also deemed essential by the Committee to improve our information about these common problems.

INTERAGENCY COMMITTEES

Although the Committee had many requests to legislate changes in existing law which would highlight specific organ-system or disease research, it chose instead to request further information related to three areas deemed important.

Interagency Committees, each "time-limited" and required to prepare a single report for Congress, are established for learning disabilities, spinal cord injuries and lung disease research.

INTERAGENCY COMMITTEE ON LEARNING DISABILITIES

Over the past several years there has been increasing concern about learning disabilities. This has been expressed through public media and many professional organizations across the spectrum of

education and health sciences. Although public awareness has been heightened, perhaps the most apparent result of this attention is public confusion. Learning disabilities reportedly afflict over 15 million of our citizens; children and adults. When not properly diagnosed and treated, individuals can suffer unnecessary life-long handicaps affecting their personal lives and careers. Tragically, it seems that misdiagnosis, and even failure to recognize learning disabilities, may occur more frequently than correct diagnosis and therapy. Another unfortunate result of the misinformation about learning disabilities is the prevalence of unproven therapies. Far too many of our citizens spend a great deal of time and money on remedies which are useless and offer false hope. Therefore, the Committee believes it is essential that we provide a means to bring together the best and brightest minds to coordinate all physiological research in learning disabilities. This will result in more appropriate and efficient use of Federal funds by targeting the high priority research. And it will likely result in vastly improved public information on these very common problems.

INTERAGENCY COMMITTEE ON SPINAL CORD INJURY

The Committee has been made acutely aware of the needs and hopes of Americans with spinal cord injuries.

Unfortunately, it is largely unknown that more than 500,000 Americans are wholely or party paralyzed from spinal cord injuries. And tragically, 20,000 more individuals fall victim to spinal cord injuries each year.

The economic costs are staggering—it is estimated that between $1 and $5 million is required to sustain an individual with a spinal cord injury over the course of his or her lifetime. This obviously represents a significant amount of our Nation's overall health care expenditures. But the cost in dollars is far overshadowed by the emotional and personal costs exacted from the spinal cord injury victims and their families.

Nonetheless, there is now considerable hope through improved rehabilitation methods and ongoing research.

The National Institutes of Health and a number of Federal handicapped programs have been critical forces in achieving this progress. Also, the efforts of private sector organizations such as the National Spinal Cord Injury Association and the Paralyzed Veterans of America have been important.

However it is clear to the Committee that more can and should be done to combat and treat spinal injuries. We know that a number of agencies have an involvement with research on such injuries and this has raised a number of questions as to the adequacy of coordination among their efforts. To assure that coordination is occurring, this amendment mandates a one-time 18 month interagency task force made up of all the relevant Federal agencies. The task force will be required to document existing spinal cord injury research and develop a plan for long-term coordination.

INTERAGENCY COMMITTEE ON LUNG DISEASES RESEARCH

Lung diseases are a major health problem in the United States. They currently rank third among the leading causes of death and

chronic respiratory symptoms are now reported by one of every five persons. Because of the large number of agencies expending funds and energies on programs that might duplicate efforts in the same area or omit important areas of investigation, the Committee believes a study should be done resulting in a recommendation to assure strong interagency overview of all federal programs dealing with lung disease and related research.

This amendment authorizes the creation of specific Interagency Subcommittee on Lung Diseases within the existing Interagency Technical Committee on Heart, Blood Vessel, Lung, and Blood Diseases. The Interagency Subcommittee on Lung Research would develop a coordinated plan for programs and activities relating to research and training concerning lung diseases, assess the adequacy of management approaches used by such institutes, departments, and agencies in carrying out such programs and activities, and recommend improved management approaches for lung disease research. This subcommittee on lung disease research would terminate within 90 days after the submission of their report.

ADDITIONAL CONCERNS—SUPPORT FOR A BIOETHICS LIBRARY AND INFORMATION RETRIEVAL SYSTEM

The rapid and spectacular advances in medical science and technology as well as in human genetics now require the thoughtful attention of scholars and students who must explore and learn about the beneficial as well as harmful consequences of these developments.

During the last four to five years, there has been an explosion in the literature on the subject of bioethics that is not readily available to interested parties throughout the United States and around the world. To avoid duplication of efforts or the rediscovery of spokes of the wheel, the federal government should provide financial support to a library housing comprehensive information on bioethical issues.

This committee intends that the Secretary, through the Director of the National Library of Medicine, shall provide a grant to an academic institution for the operation of a bioethics library and information retrieval system which shall function as a referral center for comprehensive information on bioethical issues. The Committee understands that at least $300,000 in federal assistance will be required annually to operate such library and information retrieval system.

DISSEMINATION OF INFORMATION REGARDING TREATMENT OF MENTALLY AND PHYSICALLY HANDICAPPED INFANTS

The Committee is concerned that adequate information on available treatment and management of a mentally handicapped infant or one with life-threatening congenital defects may not be easily accessible to physicians and parents confronted with such birth. The Committee therefore requests that the Public Health Service examine and promote means of facilitating the dissemination to parents and physicians of information regarding treatment and therapies available to such infants.

ORGAN SITE PROGRAM

The Committee is aware of the vigorous debate which has occurred over the last three years with regard to the Cancer Institute's Organ Site program. The Cancer Advisory Board has recently unanimously approved a comprehensive set of recommendations for restructuring the program. The recommendations include:

ORGANIZATION

That a single Organ Systems Coordinating Center (OSCC)—external but coordinated with the NCI—be established through open competition in response to an NCI RFA for the administration of an Organ Systems Program (OSP). The OSP will consist of Organ Systems Working Groups targeted to the prostate, bladder, pancreas, large bowel, breast, and any future sites or systems that may be selected.

That the OSCC develop criteria and guidelines to initiate, operate, and—when necessary—terminate individual Working Groups, with NCAB review.

That planning for the Organ Systems Program should take place with consideration of the possible need to establish other Working Groups as feasible, e.g. the upper respiratory tract and central nervous system.

That the Working Groups carry out program planning, develop and stimulate research initiatives. The Groups also will hold workshops, seminars, etc. in order to have extensive communications with the scientific community.

That the Working Groups be informed of NCI's research in their respective areas.

That the OSCC shall assist the Working Groups in this informational overview.

REVIEW

That the NCAB reaffirm separation of review from program in the Organ Systems Program.

That an appropriate mechanism for review of Organ Systems Program grant applications be established, taking note of the multidisciplinary and programmatic nature of these grants. This may necessitate the creation, within the Division of Extramural Activities of the NCI, of a special review group (or groups) to handle grant applications to the OSP.

FUNDING

That the NCI continue to provide funds, as available, for continuing the OSP at a level approximately equal to that of the previous funding for the OSP including the Breast Cancer Task Force.

That the OSCC's funding will be adequate to provide all Working Groups with appropriate resources to carry out their designated missions.

That the NCAB/OSP Subcommittee will advise the NCAB Planning and Budget Committee regarding budget recommendations.

The Committee is pleased to see these issues being resolved and views with favor funding as resources permit for organ site re-

search related to the breast, pancreas, prostate, large bowel, and the bladder.

CANCER EDUCATION PROGRAM

The Committee is impressed that cancer education programs, designed to teach prevention, early detection and diagnosis of cancer to medical and dental students have proven effective. Teaching the bases of coordinated, multidisciplinary cancer management to students will result in improved patient care by health professionals in all disciplines. The Committee expects the NCI will continue funding cancer education programs.

NUCLEAR IMAGING TECHNOLOGIES

The Committee is concerned that the health implications of the use of NMR, Cat Scans and ultra sound may not be fully known and requests that the director of N.I.H. and the commissioner of FDA provide the Committee on Labor and Human Resources of the Senate with information on the nature, extent and conclusions of research into the safety both to the patient and practitioner of these nuclear imaging technologies.

VII. Budget Estimate

U.S. Congress,
Congressional Budget Office,
Washington, D.C., May 16, 1983.

Hon. Orrin G. Hatch,
Chairman, Committee on Labor and Human Resources,
U.S. Senate,
Washington, D.C.

Dear Mr. Chairman: Pursuant to Section 403 of the Congressional Budget Act of 1974, the Congressional Budget Office has prepared the attached cost estimate for S. 773, the Biomedical Research, Training, and Medical Library Assistance Amendments of 1983, as ordered reported by the Senate Committee on Labor and Human Resources on April 13, 1983.

Should the Committee so desire, we would be pleased to provide further details on this estimate.

Sincerely,

James Blum
(For Alice M. Rivlin, Director).

Congressional Budget Office—Cost Estimate

1. Bill No.: S. 773.
2. Bill title: The Biomedical Research, Training, and Medical Library Assistance Amendments of 1983.
3. Bill status: As ordered reported by the Senate Committee on Labor and Human Resources on April 13, 1983.
4. Bill purpose: The bill would revise and extend programs relating to biomedical research, research training, and medical library assistance to establish a National Institute of Arthritis and Musculoskeletal and Skin Diseases, and for other purposes.
5. Cost estimate:

[By fiscal year, in millions of dollars]

	1984	1985	1986	1987	1988
Authorization levels: Medical library assistance (390)	10.5	11.0	11.6	.....	.....
National Cancer Institute:					
Cancer control programs (410(a))	58.8	61.7	64.8	.....	.....
Other programs (410(a))	947.4	994.8	1,044.5	.....	.....
National Heart, Lung, and Blood Institute:					
Control programs (414(b))	49.9	52.4	55.0	.....	.....
Other programs (419B)	574.1	602.8	632.9	.....	.....
Data systems and clearinghouses:					
Diabetes (435(c)(2))	2.0	2.0	2.0	.....	.....
Arthritis and musculoskeletal (439(a))	2.0	3.0	3.6	.....	.....
Diabetes research and training centers (435(d))	20.0	20.0	20.0	.....	.....
Advisory boards (437(k)):					
Diabetes	0.3	0.3	0.3	.....	.....
Digestive diseases	0.3	0.3	0.3	.....	.....
Kidney and urologic diseases	0.3	0.3	0.3	.....	.....
Arthritis	0.3	0.3	0.3	.....	.....
National research service awards (472)	195.0	204.8	215.0	.....	.....
Arthritis and musculoskeletal diseases demonstration projects (496)	5.0	5.0	5.0	.....	.....
Arthritis and musculoskeletal diseases centers (497)	12.0	15.0	18.0	.....	.....
Total Authorization Levels	1,877.9	1,973.7	2,073.6	.....	.....
Estimated outlays: Medical library assistance (390)	6.9	10.0	11.2	3.9	0.9
National Cancer Institute:					
Cancer control programs (410(a))	33.7	56.2	62.6	27.4	4.7
Other programs (410(a))	542.9	905.4	1,009.4	441.9	75.7
National Heart, Lung, and Blood Institute:					
Control programs (414(b))	26.1	47.1	53.1	25.9	4.5
Other programs (419B)	300.8	541.5	610.4	298.5	52.2
Data systems and clearinghouses:					
Diabetes (435(c)(2))	1.1	1.9	2.0	0.9	0.1
Arthritis and musculoskeletal (439(a))	1.1	2.4	3.2	1.5	0.2
Diabetes research and training centers (435(d))	11.1	18.6	19.8	8.9	1.4
Advisory boards (437(k)):					
Diabetes	0.2	0.3	0.3	0.1	.....
Digestive diseases	0.2	0.3	0.3	0.1	.....
Kidney and urologic diseases	0.2	0.3	0.3	0.1	.....
Arthritis	0.2	0.3	0.3	0.1	.....
National research service awards (472)	104.9	185.5	209.6	98.6	16.1
Arthritis and Musculoskeletal diseases demonstration projects (496)	2.8	4.7	5.0	2.2	0.3
Arthritis and musculoskeletal diseases centers (497)	6.7	12.8	16.4	7.8	1.2
Total estimated outlays	1,038.9	1,787.3	2,003.9	917.9	157.3

The costs of this bill fall within function 550.

Basis for Estimates: All authorization levels are stated in the bill. Authorized amounts are assumed to be fully appropriated at the beginning of each fiscal year. Outlays are estimated using spendout rates computed by CBO on the basis of appropriate recent program data.

6. Estimated cost to State and local governments: The budgets of the state and local governments would not be affected directly by the enactment of this bill.

7. Estimate comparison: None.

8. Previous CBO estimate: None.

9. Estimate prepared by: Hinda Ripps Chaikind (226–2820)

10. Estimate approved by: C. G. Nickols (For James L. Blum Assistant Director for Budget Analysis).

VII. Regulatory Budget Statement

The Committee has determined that there will be minimal increase in regulatory burden of paperwork imposed by this bill. The creation and function of the President's Council for Health Sciences Research will require no new regulations or paperwork on the part of the Executive Branch, or the public. It will publish one report at the end of its two year term.

The revision of statutory authorities within the NIH can be accomplished within present regulations.

VIII. Tabulation of Votes Cast in Committee

The motion to favorably report the bill to the Senate was passed unanimously by voice of the Committee.

IX. S. 773—Biomedical Research, Training, and Medical Library Assistance Amendments of 1983 as Reported by the Senate Committee on Labor and Human Resources

SECTION-BY-SECTION ANALYSIS

Section 1 of the bill cites the Act as the "Biomedical Research, Training, and Medical Library Assistance Amendments of 1983".

Section 2 of the bill identifies all references in the bill as being made to provisions of the Public Health Service Act (PHSA), except as otherwise specifically provided.

TITLE I—NATIONAL INSTITUTES OF HEALTH

Section 101 of the bill amends various sections of Title IV of the PHSA pertaining to cancer programs. It amends section 401(a)(1) to require the Secretary to conduct and promote research, investigations, experiments, and studies relating to the continuing care of cancer patients and their families. It also amends section 401(b)(1) to remove some of the restrictions on purchase of radium by the Secretary. Section 403 is amended to add developmental research to the list of Cancer Control program responsibilities, and to conform to section 401 with respect to programs to support the continuing care of the cancer patient. Section 404, outlining the duties of the Director of the National Cancer Institute (NCI) in carrying out the National Cancer Program, is amended in subsection (a) to require the continued maintenance and operation of the International Cancer Research Data Bank, including the provision that information be disseminated through systems accessible to the public, general practitioners, and oncologic investigators. Section 404(a) is also amended to add a new paragraph requiring the NCI Director to publicize widely the availability of NCI information on the prevention, diagnosis, and treatment of cancer. Section 404(b) is amended to require the NCI Director to consult with the Secretary regarding the appointment of advisory committees and the awarding of construction grants. Section 405, concerning scientific review of NCI research grants and programs, is amended to allow the NCI Director to approve grants without advisory board recommendation if the direct costs do not exceed $50,000 (instead of the current $35,000). Section 406, concerning National Cancer Research and

Demonstration Centers, is amended to extend from three years to five years the maximum period for both the initial support and any extension of that support of cancer centers. Section 410 is amended to extend the authorization of appropriations for NCI as follows: for programs other than Cancer Control Programs, $902,315,000 for FY83, $947,430,750 for FY84, $994,802,288 for FY85, and $1,044,542,402 for FY86; for Cancer Control Programs, $56,000,000 for FY83, $58,800,000 for FY84, $61,740,000 for FY85, and $64,827,000 for FY86.

Section 102 of the bill amends various sections of Title IV of the PHSA concerning heart, blood vessel, lung, and blood diseases research programs of the National Heart, Lung, and Blood Institute (NHLBI). Section 413, concerning the National Heart, Blood Vessel, Lung and Blood Diseases and Blood Resources Program, is amended in subsection (a) to include research and study programs on specific hemolytic diseases, such as sickle cell anemia and Cooley's anemia. Subsection (b) is amended to delete a provision that requires the NHLBI Director to include projected personnel requirements and recommended funding levels in the annual five-year program plan. Section 415(b), concerning cooperative agreements for developing National Research and Demonstration Centers for Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources, is amended to require the Director to consult with the National Heart, Lung, and Blood Advisory Council concerning the extension of support for such centers. Section 419A(c), concerning administrative procedures for NHLBI research grant approval, is amended to allow the NHLBI Director to approve grants without Advisory Council recommendation if the direct costs do not exceed $50,000 (instead of the current $35,000). Section 414(b) is amended to extend the authorization of appropriations for heart, blood vessel, lung, and blood disease prevention and control programs as follows: $47,500,000 for FY83, $49,875,000 for FY84, and $52,368,750 for FY85, and $54,987,188 for FY86. Section 419B is amended to extend the authorization of appropriations for the rest of NHLBI programs as follows: $546,722,000 for FY83, $574,058,100 for FY84, $602,761,005 for FY85, and $632,899,055 for FY86.

Section 103 of the bill amends section 435 of the PHSA to extend the authorization of appropriations for the Diabetes Data Group and the Diabetes Information Clearinghouse by authorizing $2,000,000 for each of the fiscal years FY84, FY85, and FY86; and to extend the authorization of appropriations for the Diabetes Research and Training Centers by authorizing $20,000,000 for each of the fiscal years FY84, FY85, and FY86.

Section 104 of the bill amends section 437 of the PHSA, which establishes the arthritis, diabetes, and digestive diseases advisory boards, by adding a provision for the establishment of a National Kidney and Urologic Diseases Advisory Board. Section 437(k) is amended to extend the authorization of appropriations for each Advisory Board by authorizing $300,000 for each of the fiscal years FY84, FY85, and FY86. The expiration date of each Advisory Board is extended to September 30, 1986.

Section 105 of the bill amends Title IV of the PHSA by adding a new Part J, establishing a National Institute of Arthritis and Musculoskeletal and Skin Diseases. The new part outlines the purpose

of the Institute, requires the preparation of a plan for a national arthritis and musculoskeletal diseases program, and requires the preparation of an annual report on the skin diseases programs of NIH. Establishment of the National Arthritis and Musculoskeletal and Skin Diseases Data System is mandated, and appropriations for the System are authorized as follows: $1,000,000 for FY84, $1,500,000 for FY85, and $1,800,000 for FY86. Establishment of the National Arthritis and Musculoskeletal and Skin Diseases Information Clearinghouse is mandated, and appropriations for the Clearinghouse are authorized as follows: $1,000,000 for FY84, $1,500,000 for FY85, and $1,800,000 for FY86. The Secretary is required to establish an Arthritis and Musculoskeletal Diseases Interagency Coordinating Committee and a Skin Diseases Interagency Coordinating Committee. The Secretary is required to establish a National Arthritis and Musculoskeletal and Skin Diseases Advisory Council. Arthritis and Musculoskeletal Diseases Demonstration Projects are described and the types of projects to be supported are listed. Appropriations for these projects are authorized at $5,000,000 for each of the fiscal years FY84, FY85, and FY86. The Director of the Institute is required to continue and expand the Multipurpose Arthritis and Musculoskeletal Diseases Centers. Responsibilities of the centers are described, and support of a center is set at a period not to exceed five years unless extended by the Director after scientific review. Appropriations for these centers are authorized as follows: $12,000,000 for FY84, $15,000,000 for FY85, and $18,000,000 for FY86. The Director is required to submit biennial reports on the Institute's activities.

Section 105 of the bill also makes conforming amendments to various sections of the PHSA dealing with the current National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) and its programs (section 431, 434, 436, 437, and 440), by removing all references to arthritis, rheumatism, and musculoskeletal and skin diseases. Section 438, concerning Arthritis Demonstration Projects and the Arthritis Data System, and section 439, concerning Multipurpose Arthritis Centers, are repealed. All functions, programs, and activities relating to arthritis and musculoskeletal and skin diseases that currently belong to NIADDK are transferred to the new Institute. The National Arthritis Advisory Board is terminated. All of the above provisions of section 105 of the bill are to take effect on October 1, 1983.

Section 105 of the bill also requires that an 18-month study be conducted on the effectiveness of the organization and administrative structures of the NIH Institutes, the effectiveness of the combinations of disease research programs in the Institutes, and the standards which should be followed in establishing new Institutes or in realigning the program areas of existing Institutes. The Secretary is directed to request the National Academy of Sciences to conduct the study. No new Institutes (other than the National Institute of Arthritis and Musculoskeletal and Skin Diseases established in this bill) are to be established earlier than six months after the study report is submitted. The Secretary is also directed to conduct a review of the disease research programs within the National Institute of Diabetes and Digestive and Kidney Diseases.

Section 106 of the bill amends Part D of Title IV of the PHSA (as amended by section 105 of this bill) to add a new section 439, providing for the development and expansion of digestive diseases research centers, and for the establishment of the National Digestive Diseases Data System and the National Digestive Diseases Information Clearinghouse, all under the National Institute of Diabetes and Digestive and Kidney Diseases. Responsibilities of the centers are described, and support of a center is set at a period not to exceed five years unless extended by the Institute Director after scientific review. Appropriations for the centers are authorized as follows: $8,000,000 for FY84, $9,000,000 for FY85, and $10,000,000 for FY86. Functions of the Data System and Information Clearinghouse are described, and appropriations are authorized as follows: $1,000,000 for FY84, $1,100,000 for FY85, and $1,200,000 for FY86.

Section 107 of the bill amends section 441 fo the PHSA, which concerns the National Institute of Child Health and Human Development, by adding "mental retardation" to the list of research and training responsibilities of the Institute, and by adding a new subsection directing the Secretary, through the Institute Director, to make grants to certain mental retardation research centers.

Section 108 of the bill makes technical and conforming amendments to various sections of the PHSA. The following sections are amended to replace references to "the Surgeon General" with references to the "Secretary": section 422, concerning dental disease research and training; section 423, concerning the administration of dental research grants and projects; section 424, concerning functions of the National Advisory Dental Research Council; section 431(a) and (b), concerning the establishment of research Institutes; section 432(a) and (b), concerning the establishment and expansion of functions of National Advisory Councils; section 433, concerning the functions of the research Institutes; section 441 (as amended by section 107 of this bill), concerning the establishment of the National Institute of Child Health and Human Development; section 442, concerning the establishment of the National Institute of General Medical Sciences; section 443(a), (b), and (c), concerning the establishment, composition, and functions of advisory councils; and section 445, concerning the preservation of existing authority of the Secretary. Technical amendment is also made to section 463(d), concerning functions of the National Institute on Aging, to replace a reference to the Former Department of Health, Education, and Welfare with a reference to the Department of Health and Human Services (DHHS).

TITLE II—OTHER PROGRAMS

Section 201 of the bill repeals section 472(c) of the PHSA, concerning the service or "payback" obligation of National Research Service Award recipients, and extends the authorization of appropriations for the Awards as follows: $195,048,000 for FY84, $204,800,400 for FY85, and $215,040,420 for FY86.

Section 202 of the bill amends two sections under Title III of the PHSA concerning the National Library of Medicine (NLM) and assistance to medical libraries. Section 383(b) is amended by deleting the requirement that the Secretary include in his annual report to

Congress a statement covering the NLM Board of Regents' recommendations on Library policy. Section 390(c) is amended to extend the authorization of appropriations under the Medical Library Assistance Act as follows: $9,763,000 for FY83, $10,500,000 for FY84, $11,025,000 for FY85, and $11,576,000 for FY86.

Section 203 of the bill has two subsections making changes in Title IV of the PHSA, and one additional subsection that does not amend existing law. Section 203(a) of the bill amends section 475 of the PHSA, concerning peer review of grant applications and contract projects, to require the Secretary to prepare and transmit to the appropriate committees of Congress an annual report on activities undertaken to improve grant, contracting, accountability, and peer review procedures at NIH. Section 203(b) of the bill adds a new section 480 to the PHSA, requiring the Directors of the NIH Institutes to notify their Advisory Boards of the status of any investigation of a grant or contract recipient, unless such a disclosure would jeopardize the investigation. Section 203(c) of the bill requires the Director of NIH to establish procedures for the appeal of determinations made on applications for research funding.

Section 204 of the bill amends section 301 of the PHSA by adding a new subsection directing the Secretary to make a grant to an academic institution to establish a research center on the health effects of nuclear energy and other new energy technologies. Appropriations are authorized at $2,000,000 for FY84 and each subsequent year.

Section 205 of the bill amends Title IV of the PHSA by adding a new section 481, concerning research for public health emergencies. In case of the appearance of a disease or disorder constituting a public health emergency, the Secretary is directed to expedite the review of research grants and contracts dealing with such a disease and is authorized to provide administrative supplemental increases in relevant existing grants and contracts.

Section 206 of the bill amends section 1302 of the PHSA, relating to health maintenance organizations, to include clinical psychologists in the provisions concerning licensed health professionals.

TITLE III—ANIMAL WELFARE IN RESEARCH STUDY FINDINGS

Section 301 of the bill requires the Secretary to arrange for an 18-month study to assist the Congress in determining whether problems amenable to legislative resolution exist with regard to the use of live animals in biomedical and behavioral research. The National Academy of Sciences will be requested to do the study. Topics to be covered in the study include: the status of the use of live animals in biomedical and behavioral research (numbers, types, research purposes, possible alternative methods); the impact on research of a requirement that laboratory facilities meet accreditation standards; the estimated expenditures for facilities to be modernized to meet accreditation standards; a review of relevant Federal and State laws and regulations; the extent to which research facilities protect animals against inhumane treatment; and an evaluation of DHHS efforts to develop alternatives to the use of live animals in research, to improve oversight of federally-funded animal research, and to insure the humane care and appro-

priate use of live animals. The report on the study is to specify such recommendations for legislation and administrative action concering research animals as the Secretary considers appropriate.

TITLE IV—REPORTS

Section 401 of the bill requires the Director of HIH to establish an Interagency Committee on Learning Disabilities, which is to review and assess Federal research priorities, activities, and findings regarding learning disabilities, including the role of central nervous system dysfunctions. The Committee, composed of representatives from various Federal agencies and the public, is to transmit a report of its activities within eighteen months, after which the Committee will terminate. The report is to discuss the population affected by learning disabilities, current research findings, and recommendations for increasing the effectiveness of research and for setting research priorities on learning disabilities.

Section 402 of the bill requires the Secretary to establish an Interagency Committee on Spinal Cord Injury within the National Institute of Neurological and Communicative Disorders and Stroke. The Committee is to plan, develop, coordiante, and implement comprehensive Federal initiatives in research on spinal cord injury. The Committee, composed of representatives from various Federal agencies, is to transmit a report of its activities within eighteen months, after which the Committee will terminate. The report is to describe existing federally-supported research projects on spinal cord injury, including information on the nature, purpose, costs, and performer of each project.

Section 403 of the bill requires the Secretary to establish a subcommittee on lung diseases within the existing Interagency Technical Committee on Heart, Blood Vessel, Lung and Blood Diseases and Blood Resources. The subcommittee is to develop a coordinated plan for the programs and activities of the various Institutes and agencies involved in lung disease research, and is to study the effectiveness of the management approaches used by these agencies. The Committee is to transmit a report of its activities within eighteen months, after which it will terminate.

Section 404 of the bill requires the Secretary to prepare and transmit to the appropriate committee of Congress a report on all NIH activities relating to alcoholism, alcohol abuse, and drug abuse conducted during FY83, specifying the number and type of personnel involved in such activities.

Section 405 of the bill requires the Secretary to establish an Interagency Task Force on Alzheimer's Disease. The Task Force is to coordinate and review research activities on Alzheimer's disease within NIH and other Federal agencies, conduct public awareness activities, and develop a research strategy and plan for increased research, especially basic science research, on Alzheimer's disease. The Committee, composed of representatives from various Federal agencies, is to transmit a report of its activities within eighteen months, after which the Committee will terminate. The report is to include recommendations for legislation and administrative action to improve the conduct of research on Alzheimer's disease and to improve programs and activities for the care and treatment of indi-

viduals afflicted with Alzheimer's disease. The Secretary is authorized to make grants to public and private nonprofit institutions to conduct research on Alzheimer's disease. Appropriations are authorized at $4,000,000 for FY84.

X. Change In Existing Law

In compliance with rule XXVI paragraph 12 of the Standard Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be ommitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

Public Health Service Act

TITLE I—SHORT TITLE AND DEFINITIONS

SHORT TITLE

Section 1. This Act may be cited as the Public Health Service Act."

* * * * * * *

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

Part A—Research and Investigation

IN GENERAL

Sec 301. [241] (a) The Secretary shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigation, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and metal diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams. In carrying out the foregoing the Secretary is authorized to—

(1) collect and make available through publications and other appropriate means, information as to, and the practical application of, such research and other activities;

(2) make available research facilities of the Service to appropriate public authorities, and to health officials and scientists engaged in special study;

(3) make grants-in-aid to universities, hospitals, laboratories and other public or private institutions, and to individuals for such research project as are recommended by the National Advisory Council, or, with respect to cancer, recommended by the National Cancer Advisory Board, or, with respect to mental health, recommended by the National Advisory Mental Health Council, or with respect to heart, blood vessel, lung, and blood diseases and blood resources, recommended by the National Heart, Lung, and Blood Advisory Council, or, with respect to dental diseases and conditions, recommended by the National

Advisory Dental Research Council, and include in the grants for any such project grants of penicillin and other antibiotic compounds for use in such project; and make, upon recommendation of the National Advisory Health Council, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research: *Provided,* That such uniform percentage, not to exceed 15 per centum, as the Secretary may determine, of the amounts provided for grants for research projects for any fiscal year through the appropriations for the National Institutes of Health may be transferred from such appropriations to a separate account to be available for such research grants-in-aid for such fiscal year;

(4) secure from time to time and for such periods as he deems advisable, the assistance and advice of experts, scholars, and consultants from the United States or abroad;

(5) for purposes of study, admit and treat at institutions, hospitals, and stations of the Service, persons not otherwise eligible for such treatment;

(6) make available, to health officials, scientists, and appropriate public and other nonprofit institutions and organizations, technical advice and assistance on the application of statistical methods to experiments, studies, and surveys in health and medical fields;

(7) enter into contracts, including contracts for research in accordance with and subject to the provisions of law applicable to contracts entered into by the military departments under title 10, United States Code, sections 2353 and 2354, except that determination, approval, and certification required thereby shall be by the Secretary of Health, Education, and Welfare; and

(8) adopt, upon recommendation of the National Advisory Health Council, or with respect to cancer, upon recommendation of the National Cancer Advisory Board or with respect to mental health, upon recommendation of the National Advisory Mental Health Council, or, with respect to heart, blood vessel, lung, and blood diseases and blood resources, upon recommendation of the National Heart, Lung, and Blood Advisory Council, or, with respect to dental diseases and conditions, upon recommendation of the National Advisory Dental Research Council, such additional means as he deems necessary or appropriate to carry out the purpose of this section.

The Secretary may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.

(b)(1) The Secretary shall conduct and may support through grants and contracts studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects. In carrying out this paragraph, the Secretary shall consult with entities of the Federal Government, outside of the Department of Health, Education, and Welfare, engaged in comparable activities. The Secretary, upon request of such an entity and under

appropriate arrangements for the payment of expenses, may conduct for such entity studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects.

(2)(A) The Secretary shall establish a comprehensive program of research into the biological effects of low-level ionizing radiation under which program the Secretary shall conduct such research and may support such research by others through grants and contracts.

(B) The Secretary shall conduct a comprehensive review of Federal programs of research on the biological effects of ionizing radiation.

(3) The Secretary shall conduct and may support through grants and contracts research and studies on human nutrition, with particular emphasis on the role of nutrition in the prevention and treatment of disease and on the maintenance and promotion of health, and programs for the dissemination of information respecting human nutrition to health professionals and the public. In carrying out activities under this paragraph, the Secretary shall provide for the coordination of such of these activities as are performed by the different divisions within the Department of Health, Education, and Welfare and shall consult with entities of the Federal Government, outside of the Department of Health, Education, and Welfare, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct and support such activities for such entity.

(4) The Secretary shall publish an annual report which contains—

(A) a list of all substances (i) which either are known to be carcinogens or may reasonably be anticipated to be carcinogens and (ii) to which a significant number of persons residing in the United States are exposed;

(B) information concerning the nature of such exposure and the estimated number of persons exposed to such substances;

(C) a statement identifying (i) each substance contained in the list under subparagraph (A) for which no effluent, ambient, or exposure standard has been established by a Federal agency, and (ii) for each effluent, ambient, or exposure standard established by a Federal agency with respect to a substance contained in the list under subparagraph (A), the extent to which, on the basis of available medical, scientific, or other data, such standard, and the implementation of such standard by the agency, decreases the risk to public health from exposure to the substance; and

(D) a description of (i) each request received during the year involved—

(I) from a Federal agency outside the Department of Health, Education, and Welfare for the Secretary, or

(II) from an entity within the Department of Health, Education, and Welfare to any other entity within the Department,

to conduct research into, or testing for, the carcinogenicity of substances or to provide information described in clause (ii) of

subparagraph (C), and (ii) how the Secretary and each such other entity, respectively, have responded to each such request.

(5) The authority of the Secretary to enter into any contract for the conduct of any study, testing, program, research, or review, or assessment under this subsection shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance in appropriation Acts.

(c)(1) The Secretary shall make a grant to an academic institution for the establishment and operation of a center to conduct research on the health effects of nuclear energy and other new energy technologies.

(2) To carry out this subsection, there are authorized to be appropriated $2,000,000 for the fiscal year ending September 30, 1984, and each of the succeeding fiscal years.

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PART I—NATIONAL LIBRARY OF MEDICINE

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BOARD OF REGENTS

SEC. 383. [277] (a) There is hereby established in the Public Health Service a Board of Regents of the National Library of Medicine (referred to in this part as the "Board") consisting of the Surgeons General of the Public Health Service, the Army, the Navy, and the Air Force, the Chief Medical Director of the Department of Medicine and Surgery of the Veterans' Administration, the Assistant Director for Biological and Medical Sciences of the National Science Foundation, and the Librarian of Congress, all of whom shall be ex officio members and ten members appointed by the Secretary. The ten appointed members shall be selected from among leaders in the various fields of the fundamental sciences, medicine, dentistry, public health, hospital administration, pharmacology, or scientific or medical library work, or in public affairs. At least six of the appointed members shall be selected from among leaders in the fields of medical, dental, or public health research or education. The Board shall annually elect one of the appointed members to serve as Chairman until the next election. The Secretary shall designate a member of the Library staff to act as executive secretary of the Board.

(b) It shall be the duty of the Board to advise, consult with, and make recommendations to the Secretary on important matters of policy in regard to the Library, including such matters as the acquisition of materials for the Library, the scope, content and organization of the Library's services, and the rules under which its materials, publications, facilities, and services shall be made available to various kinds of users [and the Secretary shall include in his annual report to the Congress a statement covering the recommendations made by the Board and the disposition thereof]. The Secretary is authorized to use the services of any member or members of the Board in connection with matters related to the work of the Library, for such periods, in addition to conference periods, as he may determine.

(c) Each appointed member of the Board shall hold office for a term of four years, except that (A) any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed for the remainder of such term, and (B) the terms of the members first taking office after the date of enactment of this part shall expire as follows: three at the end of four years after such date, three at the end of three years after such date, two at the end of two years after such date, and two at the end of one year after such date, as designated by the Secretary at the time of appointment. None of the appointed members shall be eligible for reappointment within one year after the end of his preceding term.

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%124.4 A110SA.052

PART J.—ASSISTANCE TO MEDICAL LIBRARIES

DECLARATION OF POLICY, STATEMENT OF PURPOSE, AND AUTHORIZATION OF APPROPRIATIONS

SEC. 390. [208b] (a) The Congress hereby finds and declares that (1) the unprecedented expansion of knowledge in the health sciences within the past two decades has brought about a massive growth in the quantity, and major changes in the nature of, biomedical information, materials, and publications; (2) there has not been a corresponding growth in the facilities and techniques necessary adequately to coordinate and disseminate among health scientists and practitioners the ever-increasing volume of knowledge and information which has been developed in the health science field; (3) much of the value of the ever-increasing volume of knowledge and information which has been, and continues to be, developed in the health science field will be lost unless proper measures are taken in the immediate future to develop facilities and techniques necessary to collect, preserve, store, process, retrieve, and facilitate the dissemination and utilization, of such knowledge and information.

(b) It is therefore the policy of this part to—

(1) assist in the training of medical librarians and other information specialists in the health sciences;

(2) assist, through grants to physicians and other practitioners in the sciences related to health, to scientists, and to public or nonprofit private institutions on behalf of such physicians, other practitioners, and scientists, in the compilation of existing, and the creation of additional, written matter which will facilitate the distribution and utilization of knowledge and information in sciences related to health;

(3) assist in the conduct of research, investigations, and demonstrations in the field of medical library science and related activities, and in the development of new techniques, systems, and equipment for processing, storing, retrieving, and distributing information in the sciences related to health;

(4) assist in establishing, expanding, and improving the basic resources of medical libraries and related facilities;

(5) assist in the development of a national system of regional medical libraries each of which would have facilities of sufficent depth and scope to supplement the services of other medical libraries within the region served by it, and

(6) provide financial support to biomedical scientific publications.

(c) For the purpose of grants and contracts under sections 393, 394, 395, 396, and 397, there are authorized to be appropriated $17,500,000 for the fiscal year ending June 30, 1975, $20,000,000 for the fiscal year ending June 30, 1976, $14,600,000 for the fiscal year ending September 30, 1978; $15,000,000 for the fiscal year ending September 30, 1979, $16,500,000 for the fiscal year ending September 30, 1980, $18,500,000 for the fiscal year ending September 30, 1981, [and] $7,500,000 for the fiscal year ending September 30, 1982, *$9,763,000 for the fiscal year ending September 30, 1983, $10,500,000 for the fiscal year ending September 30, 1984, $11,025,000 for the fiscal year ending September 30, 1985, and $11,576,000 for the fiscal year ending September 30, 1986.*

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TITLE IV—NATIONAL RESEARCH INSTITUTES

PART A—NATIONAL CANCER INSTITUTE

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CANCER RESEARCH AND OTHER ACTIVITIES

SEC. 401. [282] (a) In carrying out the purposes of section 301 with respect to cancer, the Secretary, through the Institute and in cooperation with the National Cancer Advisory Board, shall—

(1) conduct, assist, and foster research, investigations, experiments, and studies relating to the cause, prevention, and methods of diagnosis and treatment of cancer, *and the continuing care of the cancer patient and the family of the cancer patient;*

(2) promote the coordination of research conducted by the Institute and similar research conducted by other agencies and organizations and by individuals;

(3) provide clinical training and instruction in technical matters relating to the diagnosis and treatment of cancer;

(4) secure for the Institute consultation services and advice of cancer experts from the United States and abroad;

(5) cooperate with State health agencies in the prevention, control, and eradication of cancer; and

(6) procure, use, and lend radium as provided in subsection (b).

(b) In carrying out subsection (a), all appropriate provisions of section 301 shall be applicable to the authority of the Secretary, and the Secretary is authorized—

(1) to purchase [radium, from time to time and] *radium* without regard to section 3709 of the Revised Statutes, and to make such radium available for the purposes of this part, both to the Service and by loan to other agencies and institutions

for such consideration and subject to such conditions as he may prescribe; and

(2) to provide the necessary facilities where training and instruction may be given in all technical matters relating to the diagnosis and treatment of cancer to persons found by the Secretary to have proper technical qualifications and designated by him for such training or instruction and to fix and pay them a per diem allowance during such training or instruction.

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CANCER CONTROL PROGRAMS

SEC. 403. [284] The Director of the Institute shall establish and support demonstration, *developmental research,* education, and other programs for the detection, diagnosis, prevention, and treatment of cancer and for *the continuing care of the cancer patient and the family of the cancer patient, including* rehabilitation and counseling respecting cancer. Programs established and supported under this section shall include—

(1) locally initiated education, *research,* and demonstration programs (and regional networks of such programs) to transmit research results and to disseminate information respecting the detection, diagnosis, prevention, and treatment of cancer and [rehabilitation and counseling] *rehabilitation, counseling, and continuing care* respecting cancer to physicians and other health professionals who provide care to individuals who have cancer;

(2) the demonstration of and the education of health professionals in—

(A) effective methods for the early detection of cancer and the identification of individuals with a high risk of developing cancer, and

(B) improved methods of patient referral to appropriate centers for early diagnosis and treatment of cancer; and

(3) the demonstration of new methods for the dissemination of information to the general public concerning the early detection and treatment of cancer and information concerning unapproved and ineffective methods, drugs, and devices for the diagnosis, prevention, treatment, and control of cancer.

DUTIES AND FUNCTIONS OF THE DIRECTOR

SEC. 404. [285] (a) The Director of the Institute in carrying out the National Cancer Program shall—

[(1) collect, analyze, and disseminate information (including information respecting nutrition programs for cancer patients and the relationship between, nutrition and cancer) useful in the prevention, diagnosis, and treatment of cancer, including the establishment, of an international cancer research, data bank to collect, catalog, store, and disseminate insofar as feasible the results of cancer research undertaken in any country for the use of any person involved in cancer research in any country;]

(1) collect, analyze, and disseminate information (including information respecting nutrition programs for cancer patients and the relationship between nutrition and cancer) useful in the prevention, diagnosis, and treatment of cancer, including the maintenance and operation of the International Cancer Research Data Bank, which shall collect, catalog, store, and disseminate insofar as feasible through the use of information systems accessible to the public, general practitioners, and oncologic investigators, the results of cancer research and treatment undertaken in any country for the use of any person involved in cancer research and treatment in any country;

(2) establish or support the large-scale production or distribution of specialized biological materials and other therapeutic substances for research and set standards of safety and care for persons using such materials;

(3) support research in the cancer field outside the United States by highly qualified foreign nationals which research can be expected to insure to the benefit of the American people; support collaborative research involving American and foreign participants' and support the training of American scientists abroad and foreign scientists in the United States;

(4) support appropriate programs of education (including continuing education) and training in fundamental sciences and clinical disciplines for investigators, physicians, and allied health professionals for participation in clinical programs relating to cancer, including the use of training stipends, fellowships, and career awards;

(5) expeditiously utilize research facilities and personnel of the National Institutes of Health for accelerated exploration of opportunities in areas of special promise;

(6) encourage and coordinate cancer research by industrial concerns where such concerns evidence a particular capability for such research;

(7) provide and contract for a program to disseminate and interpret, on a current basis, for practitioners and other health professionals, scientists, and the general public, scientific and other information respecting the cause, prevention, diagnosis, and treatment of cancer,

(8)(A) prepare and submit, dirctly to the President for review and transmittal to Congress, an annual budget estimate (including an estimate of the number and type of personnel needs for the National Cancer Institute) for the National Cancer Program, after reasonable opportunity for comment (but without change) by the Secretary, the Director of the National Institutes of Health, and the National Cancer Advisory Board; and (B) receive from the President and the Office of Management and Budget directly all funds appropriated by Congress for obligation and expenditure by the Institute; [and]

(9) as soon as practicable after the end of each fiscal year, prepare in consultation with the National Cancer Advisory Board and submit to the Secretary, for simultaneous transmittal, not later than November 30 of each year, to the President and to the Congress, a report on the activities, progress, and accomplishments under the National Cancer Program during

the preceding fiscal year, which shall include a report on the progress, activities, and accomplishments of, and expenditures for, the information services of the Program, and a plan for the Program during the next five years [.]; *and*

(10) insofar as feasible, publicize and promote, through domestic and foreign media which is disseminated to general practitioners and oncologic investigators, the existence and availability of the Institute's publications and information systems relating to the prevention, diagnosis, and treatment of cancer.

(b) The Director of the Institute (after consultation with the National Cancer Advisory Board) in carrying out his functions in administering the National Cancer Program and without regard to any other provision of this Act is authorized—

(1) to obtain (in accordance with section 3109 of title 5, United States Code and if authorized by the National Cancer Advisory Board, but without regard to the limitation in such section on the number of days or the period of such service) the services of not more than one hundred and fifty-one experts or consultants who have scientific or professional qualifications;

(2) to acquire, construct, improve, repair, operate, and maintain cancer centers, laboratories, research, and other necessary facilities and equipment, and related accommodations as may be necessary, and such other real or personal property (including patents) as the Director deems necessary to acquire without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the Institute for a period not to exceed ten years;

(3) to appoint, *in consultation with the Secretary,* one or more advisory committees composed of such private citizens and officials of Federal, State, and local governments as he deems desirable to advise him with respect to his functions;

(4) to utilize, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, with or without reimbursement therefor;

(5) to accept voluntary and uncompensated services;

(6) to accept unconditional gifts, or donations of services, money, or property, real, personal, or mixed, tangible or intangible;

(7) to enter into such contracts, leases, cooperative agreements, or other transactions, without regard to sections 3648 and 3709 of the Revised Statues of the United States (31 U.S.C. 529, 41 U.S.C. 5), as may be necessary in the conduct of his functions, with any public agency, or with any person, firm, association, corporation, or educational institution;

(8) to take necessary action to insure that all channels for the dissemination and exchange of scientific knowledge and information are maintained between the Institute and the other scientific, medical, and biomedical disciplines and organizations nationally and internationally;

(9) to award grants, *in consultation with the Secretary,* for new construction as well as alterations and renovations for improvement of basic research laboratory facilities, including those related to biohazard control, as deemed necessary for the National Cancer Program; and

(10) to call special meetings to the National Cancer Advisory Board at such times and in such places as the Director deems necessary in order to consult with, obtain advice from, or to secure the approval of projects, programs, or other actions to be undertaken without delay in order to gain maximum benefit from a new scientific or technical finding.

SCIENTIFIC REVIEW

SEC. 405. [286] (a) The Director of the Institute shall, by regulation, provide for proper scientific review of all research grants and programs over which he has authority (1) by utilizing, to the maximum extent possible, appropriate peer review groups established within the National Institutes of Health and composed principally of non-Federal scientists and other experts in the scientific and disease fields, and (2) when appropriate, by establishing, with the approval of the National Cancer Advisory Board and the Director of the National Institutes of Health, other formal peer review groups as may be required.

(b) Under procedures approved by the Director of the National Institutes of Health, the Director of the National Cancer Institute may approve grants under this Act of cancer research or training—

(1) if the direct costs of such research and training do not exceed [$35,000,] *$50,000,* but only after appropriate review for scientific merit, and

(2) if the direct costs of such research and training exceed [$35,000,] *$50,000,* but only after appropriate review for scientific merit and recommendation for approval by the National Cancer Advisory Board under section 407(b)(3).

NATIONAL CANCER RESEARCH AND DEMONSTRATION CENTERS

SEC. 406. [286a] (a) The Director of the Institute is authorized to provide for the establishment of new centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods for cancer. Such centers may be supported under subsection (b) or under any other applicable provision of law.

(b) The Director of the Institute, under policies established by the Director of the National Institutes of Health and after consultation with the National Cancer Advisory Board, is authorized to enter into cooperative agreements with public or private nonprofit agencies or institutions to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for existing or new centers (including, but not limited to, centers established under subsection (a)) for basic and clinical research into, training in, and demonstration of advanced diagnostic, prevention, and treatment methods for cancer. Federal payments under this subsection in support of such cooperative agreements may be used for (1) construction (notwithstanding any limitation under section

477), (2) staffing and other basic operating costs, including such patient care costs as are required for research, (3) clinical training (including clinical training for allied health professionals, continuing education for health professionals and allied health professions personnel, and information programs for the public respecting cancer, and (4) demonstration purposes. The aggregate of payments (other than payments for construction) made to any center in support of such an agreement for its costs (other than indirect costs) described in the first sentence may not exceed $5,000,000 in any fiscal year, except that if in any fiscal year there is an increase, as reflected in the Consumer Price Index published by the Bureau of Labor Statistics, in the cost of a center for which payments may be made under such an agreement, the aggregate of payments in such year for such center may exceed $5,000,000 to include such increase and any such increase in any preceding fiscal year for which payments were made to such center under such an agreement to the extent that such increase resulted in payments in excess of $5,000,000. As used in this section, the term "construction" does not include the acquisition of land, and the term "training" does not include research training for which fellowship support may be provided under section 472. Support of a center under this section may be for a period of not to exceed [three] *five* years and may be extended by the Director of the Institute, *in consultation with the National Cancer Advisory Board,* for additional periods of not more than [three] *five* years each, after review of the operations of such center by an appropriate scientic review group established by the Director of the Institute.

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AUTHORIZATION OF APPROPRIATIONS

SEC. 410. [286e] (a) For the purpose of carrying out this part (other than section 403), there are authorized to be appropriated $400,000,000 for the fiscal year ending June 30, 1972; $500,000,000 for the fiscal year ending June 30, 1973; $600,000,000 for the fiscal year ending June 30, 1974; $750,000,000 for the fiscal year ending June 30, 1975; $830,000,000 for the fiscal year ending June 30, 1976; $985,000,000 for the fiscal year ending September 30, 1977; $923,590,000 for the fiscal year ending September 30, 1978; $924,500,000 for the fiscal year ending September 30, 1979; $927,000,000 for the fiscal year ending September 30, 1980; $1,015,700,000 for the fiscal year ending September 30, 1981; [and] $1,109,000,000 for the fiscal year ending September 30, 1982; *$902,315,000 for the fiscal year ending September 30, 1983; $947,430,750 for the fiscal year ending September 30, 1984; $994,802,288 for the fiscal year ending September 30, 1985; $1,044,542,402 for the fiscal year ending September 30, 1986.*

(b) There are authorized to be appropriated to carry out section 403, $20,000,000 for the fiscal year ending June 30, 1972; $30,000,000 for the fiscal year ending June 30, 1973; $40,000,000 for the fiscal year ending June 30, 1974; $53,500,000 for the fiscal year ending June 30, 1975; $68,500,000 for the fiscal year ending June 30, 1976; $88,500,000 for the fiscal year ending September 30, 1977; $84,560,000 for the fiscal year ending September 30, 1978;

$90,500,000 for the fiscal year ending September 30, 1979; $103,000,000 for the fiscal year ending September 30, 1980; $112,900,000 for the fiscal year ending September 30, 1981; [and] $123,200,000 for the fiscal year ending September 30, 1982; *$56,000,000 for the fiscal year ending September 30, 1983; $58,800,000 for the fiscal year ending September 30, 1984; $61,740,000 for the fiscal year ending September 30, 1985; $64,827,000 for the fiscal year ending September 30, 1986.*

(c) The authority of the Secretary to enter into any contract for the conduct of a program under section 404(a)(7) shall be effective for any fiscal year only to such extend or in such amounts as are provided in advance in appropriation Acts.

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NATIONAL HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASES AND BLOOD RESOURCES PROGRAM

SEC. 413. [287b] (a) The Director of the Institute, with the advice of the Council, shall develop a plan for a National Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources Program (hereafter in this part referred to as the "Program") to expand, intensify, and coordinate the activities of the Institute respecting heart, blood vessel, lung, and blood diseases and blood resources (including its activities under section 412) and shall carry out the Program in accordance with such plan. The Program shall be coordinated with the other research institutes of the National Institutes of Health to the extent that they have responsibilities respecting such diseases and shall provide for—

(1) investigation into the epidemiology, etiology, and prevention of all forms and aspects of heart, blood vessel, lung, and blood diseases, including investigations into the social, environmental, behavioral, nutritional, biological, and genetic determinants and influences involved in the epidemiology, etiology, and prevention of such diseases;

(2) studies and research into the basic biological processes and mechanisms involved in the underlying normal and abnormal heart, blood vessel, lung, and blood phenomena;

(3) research into the development, trial, and evaluation of techniques, drugs, and devices (including computers) used in, and approaches to, the diagnosis, treatment (including emergency medical service), and prevention of heart, blood vessel, lung, and blood diseases and the rehabilitation of patients suffering from such diseases;

(4) establishment of programs that will focus and apply scientific and technological efforts involving biological, physical, and engineering sciences to all facets of heart, blood vessel, lung, and blood diseases with emphasis on refinement, development, and evaluation of technological devices that will assist, replace, or monitor vital organs and improve instrumentation for detection, diagnosis, and treatment of those diseases;

(5) establishment of programs for the conduct and direction of field studies, large-scale testing and evaluation, and demonstration of preventive, diagnostic, therapeutic, and rehabilita-

tive approaches to, and emergency medical services for, such diseases;

(6) studies and research into blood diseases and blood, and into the use of blood for clinical purposes and all aspects of the management of its resources in this country, including the collection, preservation, fractionalization, and distribution of it and its products;

(7) the education and training of scientists, clinicians, and educators, in fields and specialties (including computer sciences) requisite to the conduct of clinical programs respecting heart, blood vessel, lung, and blood diseases and blood resources;

(8) public and professional education relating to all aspects of such diseases and the use of blood and blood products and the management of blood resources;

(9) establishment of programs for study and research into heart, blood vessel, lung, and blood diseases of children (including cystic fibrosis, hvaline membrane, [and hemolytic and hemophilic diseases] *hemolytic diseases, such as sickle cell anemia and Cocley's anemia, and hemophilic diseases*) and for the development and demonstration of diagnostic, treatment, and preventive approaches to these diseases; and

(10) establishment of programs for study, research, development, demonstrations and evaluation of emergency medical services for people who become critically ill in connection with heart, blood vessel, lung, and blood diseases, which programs shall include programs for (A) the training of paraprofessionals in (i) emergency treatment procedures, and (ii) utilization and operation of emergency medical equipment, (B) the development and operation of (i) mobile critical care units (including helicopters and other airborne units where appropriate), (ii) radio, telecommunications, and other means of communications, and (iii) electronic monitoring systems, and (C) the coordination with other community services and agencies in the joint use of all forms of emergency vehicles, communications systems, and other appropriate services.

The Program shall give special emphasis to the continued development in the Institute of programs relating to atherosclerosis, hypertension, thrombosis, and congenital abnormalities of the blood vessels as causes of stroke, and to effective coordination of such programs with related stroke programs in the National Institute of Neurological Diseases and Stroke.

(b)(1) The plan required by subsection (a) of this section shall (A) be developed within one hundred and eighty days after the effective date of this section, (B) be transmitted to the Congress, and (C) set out the Institute's staff requirements to carry out the Program and recommendations for appropriations for the Program.

(2) The Director of the Institute shall, as soon a practicable after to end of each fiscal year, prepare in consultation with the Council and submit a report to the Secretary, for simultaneous transmittal by the Secretary, not later than November 30 of each year, to the President and to the Congress, on the activities, progress, and accomplishments under the Program during the preceding fiscal year and a plan for the Program during the next five years [Each such

plan shall contain (A) an estimate of the number and type of personnel which will be required by the Institute to carry out the Program during the five years with respect to which the plan is submitted, and (B) recommendations for appropriations to carry out the Program during such five years.]

(c) In carrying out the Program, the Director of the Institute, under policies established by the Director of the National Institutes of Health and after consultations with the Council and without regard to any other provision of this Act, may—

(1) if authorized by the Council, obtain (in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the number of days or the period of such service) the services of not more than one hundred experts or consultants who have scientific or professional qualifications;

(2) acquire, construct, improve, repair, operate, alter, renovate, and maintain heart, blood vessel, lung, and blood disease and blood resource laboratory, research, training, and other necessary facilities and equipment, and related accommodations as may be necessary, and such other real or personal property (including patents) as the Director deems necessary; and acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise, through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the Institute for a period not to exceed ten years; and

(3) enter into such contracts, leases, cooperative agreements, or other transactions, without regard to sections 3648 and 3709 of the Revised Statutes of the United States (31 U.S.C. 529, 41 U.S.C. 5), as may be necessary in the conduct of his functions, with any public agency, or with any person, firm, association, corporation, or educational institution.

(d) There shall be in the Institute an Assistant Director for Prevention, Education, and Control who shall be appointed by the Director of the Institute. The Director of the Institute, acting through the Assistant Director for Prevention, Education, and Control shall conduct a program to provide on a timely basis the public and the health professions with health information with regard to cardiovascular and, blood and pulmonary disease and blood resources. In the conduct of such program, special emphasis shall be placed upon dissemination of information regarding diet and nutrition, environmental pollutants, exercise, stress, hypertension, cigarette smoking, weight control, and other factors affecting the prevention of arterisclerosis and aother cardiovascular diseases and of pulmonary and blood diseases.

HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASE PREVENTION AND CONTROL PROGRAMS

Sec. 414. [287c] (a) The Director of the Institute, under policies established by the Director of the National Institutes of Health and after consultation with the Council, shall establish programs as

necessary for cooperation with other Federal health agencies, State, local, and regional public health agencies, and nonprofit private health agencies in the diagnosis, prevention, and treatment (including the provision of emergency medical services) of heart, blood vessel, lung, and blood diseases, appropriately emphasizing the prevention, diagnosis, and treatment of such diseases of children.

(b) There is authorized to be appropriated to carry out this section $25,000,000 for the fiscal year ending June 30, 1973, $35,000,000 for the fiscal year ending June 30, 1974, $45,000,000 for the fiscal year ending June 30, 1975, $10,000,000 for fiscal year 1976, $30,000,000 for the fiscal year ending September 30, 1977, $30,000,000 for the fiscal year ending September 30, 1978, $40,000,000 for the fiscal year ending September 30, 1979, $45,000,000 for the fiscal year ending September 30, 1980, $49,300,000 for the fiscal year ending September 30, 1981, [and] $53,800,000 for the fiscal year ending September 30, 1982, *$47,500,000 for the fiscal year ending September 30, 1983, $49,875,000 for the fiscal year ending September 30, 1984, $52,368,750 for the fiscal year ending September 30, 1985, and $54,987,188 for the fiscal year ending September 30, 1986.*

NATIONAL RESEARCH AND DEMONSTRATION CENTERS FOR HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASES AND BLOOD RESOURCES

SEC. [287d] (a)(1) The Director of the Institute may provide for the development of—

(A) ten new centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods (including methods of providing emergency medical services) for heart and blood vessel diseases,

(B) ten new centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods (including methods of providing emergency medical services) for lung diseases (including bronchitis, emphysema, asthma, cystic fibrosis, and other lung diseases of children), and

(C) ten new centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods (including methods of providing emergency medical services) for blood diseases and research into blood, in the use of blood products and in the management of blood resources.

(2) The centers developed under paragraph (1) shall, in addition to being utilized for research, training, and demonstrations, be utilized for the following prevention programs for cardiovascular, pulmonary, and blood diseases:

(A) Programs to develop improved methods of detecting individuals with a high risk of developing cardiovascular, pulmonary, and blood diseases.

(B) Programs to develop improved methods of intervention against those factors which cause individuals to have a high risk of developing such diseases.

(C) Programs to develop health professions and allied health professions personnel highly skilled in the prevention of such diseases.

(D) Programs to develop improved methods of providing emergency medical services for persons with such diseases.

(E) Programs of continuing education for health and allied health professionals in the diagnosis, prevention, and treatment of such diseases and information programs for the public respecting the prevention and early diagnosis and treatment of such diseases.

(3) Centers developed under this subsection may be supported under subsection (b) or under any other applicable provision of law. The research, training, and demonstration activities carried out through any such center may relate to any one or more of the diseases referred to in paragraph (1) of this subsection.

(b) The Director of the Institute, under policies established by the Director of the National Institutes of Health and after consultation with the Council, may enter into cooperative agreements with public or nonprofit private agencies or institutions to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for, existing or new centers (including centers established under subsection (a)) for basic or clinical research into, training in, and demonstration of, the management of blood resources and advanced diagnostic, prevention, and treatment methods for heart, blood vessel, lung, or blood diseases. Funds paid to centers under cooperative agreements under this subsection may be used for—

(1) construction, notwithstanding section 477,

(2) staffing and other basic operating costs, including such patient care costs as are required for research,

(3) training, including training for allied health professions personnel, and

(4) demonstration purposes.

The aggregate of payments (other than payments for construction) made to any center under such an agreement for its costs (other than indirect costs) described in the first sentence may not exceed $5,000,000 in any fiscal year, except that if in any fiscal year there is an increase, as reflected in the Consumer Price Index published by the Bureau of Labor Statistics, in the costs of a center for which payments may be made under such an agreement, the aggregate of payments in such year for such center may exceed $5,000,000 to include such increase and any such increase in any preceding fiscal year for which payments were made to such center under such an agreement to the extent that such increase resulted in payments in excess of $5,000,000. Support of a center under this subsection may be for a period of not to exceed five years and may be extended by the Director of the Institute *in consultation with the National Heart, Lung, and Blood Advisory Council,* for additional periods of not more than five years each, after review of the operations of such center by an appropriate scientific review group established by the Director. As used in this section, the term "construction" does not include the acquistion of land; and the term "training"

does not include research training for which fellowship support may be provided under section 472.

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ADMINISTRATION

SEC. 419A. [287h] (a) In carrying out the provisions of section 412 all appropriate provisions of section 301 shall be applicable to the authority of the Secretary, and except as provided in subsection (c), grants-in-aid for heart, blood vessel, lung, and blood disease research and training projects and projects with respect to the use of blood and blood products and the management of blood resources shall be made only after review and recommendation of the Council.

(b) The Secretary may, in accordance with section 501, accept conditional gifts for study, investigation, or research into the cause, prevention, or methods of diagnosis or treatment of heart, blood vessel, lung, and blood diseases and into the use of blood and blood products and the management of blood resources, or for the acquisition of grounds or for the erection, equipment, or maintenance of premises, buildings or equipment of the Institute. Donations of $50,000 or over for carrying out the purposes of this part may be acknowledged by the establishment within the Institute of suitable memorials to the donors.

(c) Under procedures approved by the Director of the National Institutes of Health, the Director of the National Heart, Lung, and Blood Institute may approve grants under this Act for research and training in heart, blood vessel, lung, and blood diseases and for research and training in the use of blood and blood products and the management of blood resources—

(1) if the direct costs of such research and training do not exceed [$35,000] *$50,000,* but only after appropriate review for scientific merit but without review and recommendation by the Council, and

(2) if the direct costs of such research and training exceed [$35,000] *$50,000,* but only after appropriate review for scientific merit and recommendation for approval by the Council.

AUTHORIZATION OF APPROPRIATIONS

SEC. 419B. [287i] For the purpose of carrying out this part (other than section 414), there is authorized to be appropriated $375,000,000 for the fiscal year ending June 30, 1973, $425,000,000 for the fiscal year ending June 30, 1974, $475,000,000 for the fiscal year ending June 30, 1975, $339,000,000 for the fiscal year 1976, $373,000,000 for the fiscal year ending September 30, 1977, $426,320,000 for the fiscal year ending September 30, 1978, $470,000,000 for the fiscal year ending September 30, 1979, $515,000,000 for the fiscal year ending September 30, 1980, $564,300,000 for the fiscal year ending September 30, 1981, [and] $616,100,000 for the fiscal year ending September 30, 1982, *$546,722,000 for the fiscal year ending September 30, 1983, $574,058,100 for the fiscal year ending September 30, 1984, $602,761,005 for the fiscal year ending September 30, 1985, and*

$632,899,055 for the fiscal year ending September 30, 1986. Of the sums appropriated under this section for any fiscal year, not less than 15 per centum of such sums shall be reserved for programs under this part respecting diseases of the lung and not less than 15 per centum of such sums shall be reserved for programs under this part for programs respecting blood diseases and blood resources.

PART C—NATIONAL INSTITUTE OF DENTAL RESEARCH

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DENTAL DISEASE RESEARCH AND TRAINING

SEC. 422. [288a] In carrying out the purposes of section 301 with respect to dental diseases and conditions the [Surgeon General] *Secretary,* through the Institute and in cooperation with the National Advisory Dental Research Council (hereafter in this part referred to as the "Council") shall—

(a) conduct, assist, and foster researches, investigations, experiments, and studies relating to the cause, prevention, and methods of diagnosis and treatment of dental diseases and conditions;

(b) promote the coordination of researches conducted by the Institute, and similar researches conducted by other agencies, organizations, and individuals;

(c) secure for the Institute consultation services and advice of persons from the United States or abroad who are experts in the field of dental diseases and conditions;

(d) cooperate with State health agencies in the prevention and control of dental diseases and conditions; and

(e) provide clinical training and instruction and establish and maintain clinical traineeships, in the Institute and elsewhere in matters relating to the diagnosis, prevention, and treatment of dental diseases and conditions with such stipends and allowances (including travel and subsistence expenses) for trainees as he may deem necessary, the number of persons receiving such training and instruction, and the number of persons holding such traineeships, to be fixed by the Council, and, in addition, provide for such training, instruction, and traineeships through grants, upon recommendations of the Council, to public and other nonprofit institutions.

ADMINISTRATION

SEC. 423. [288b] (a) In carrying out the provisions of section 422 all appropriate provisions of section 301 shall be applicable to the authority of the [Surgeon General] *Secretary,* and grants-in-aid for dental research and training projects shall be made only after review and recommendation of the Council made pursuant to section 424.

(b) The Surgeon General shall recommend to the Secretary acceptance of conditional gifts, pursuant to section 501, for study, investigation, or research into the cause, prevention, or methods of diagnosis or treatment of dental diseases and conditions, or for the acquisition of grounds or for the erection, equipment, or mainte-

nance of premises, buildings, or equipment of the Institute. Donations of $50,000 or over for carrying out the purposes of this part may be acknowledged by the establishment within the Institute of suitable memorials to the donors.

FUNCTIONS OF THE COUNCIL

SEC. 424. [288c] The Council is authorized to—

(a) review research projects or programs submitted to or initiated by it relating to the study of the cause, prevention, or methods of diagnosis and treatment of dental diseases and conditions, and certify approval to the [Surgeon General] *Secretary* for prosecution under section 422(a) hereof, of any such projects which it believes show promise of making valuable contributions to human knowledge with respect to the cause, prevention, or methods of diagnosis and treatment of dental diseases and conditions;

(b) collect information as to studies which are being carried on in the United States or any other country as to the cause, prevention, or methods of diagnosis or treatment of dental diseases and conditions, by correspondence or by personal investigation of such studies, and with the approval of the [Surgeon General] *Secretary* make available such information through appropriate publications for the benefit of health agencies and organizations (public or private), physicians, dentists, or any other scientists, and for the information of the general public;

(c) review applications from any university, hospital, laboratory, or other institution, whether public or private, or from individuals, for grants-in-aid for research projects relating to dental diseases and conditions, and certify to the [Surgeon General] *Secretary* its approval of grants-in-aid in the cases of such projects which show promise of making valuable contributions to human knowledge with respect to the cause, prevention, or methods of diagnosis of treatment of dental diseases and conditions:

(d) recommend to the [Surgeon General] *Secretary* for acceptance conditional gifts pursuant to secton 501 for carrying out the purposes of this part;

(e) make recommendations to the [Surgeon General] *Secretary* with respect to carrying out the provisions of this part; and

(f) review applications from any public or other nonprofit in stitution for grants-in-aid for training, instruction, and traineeships in matters relating to the diagnosis, prevention, and treatment of dental diseases and conditions, and certify to the [Surgeon General] *Secretary* its approval of such applications for grants-in-aid as it determines will best carry out the purposes of this Act.

PART D—NATIONAL INSTITUTE OF [ARTHRITIS, DIABETES] *DIABETES* AND DIGESTIVE AND KIDNEY DISEASES, NATIONAL INSTITUTE OF NEUROLOGICAL DISEASES AND STROKE, AND OTHER INSTITUTES

ESTABISHMENT OF INSTITUTES

SEC. 431 [289a] (a) The [Surgeon General] *Secretary* shall establish in the Public Health Service an institute for research on [arthritis, rheumatism, and] metabolic diseases, and an institute for research on neurological diseases (including epilepsy, cerebral palsy, and multiple sclerosis) and blindness, and he shall also establish a national advisory council or committee for each such institute to advise, consult with, and make recommendations to him with respect to the activities of the institute with which each council or committee is concerned.

(b) The [Surgeon General is authorized with the approval of the Secretary] *Secretary is authorized* to establish in the Public Health Service one or more additional institutes to conduct and support scientific research and professional training relating to the cause, prevention, and methods of diagnosis and treatment of other particular diseases or groups of diseases (including poliomyelitis and leprosy) whenever the [Surgeon General] *Secretary* determines that such action is necessary to effectuate fully the purposes of section 301 with respect to such disease or diseases. Any institute established pursuant to this subsection may in like manner be abolished and its functions transferred elsewhere in the Public Health Service upon a finding by the [Surgeon General] *Secretary* that a separate institute is no longer required for such purposes. in lieu of the establishment pursuant to this subsection of an additional institute with respect to any disease or diseases, the [Surgeon General] *Secretary* may expand the functions of any institute established under subsection (a) of this section or under any other provision of this Act so as to include functions with respect to such disease or diseases and to terminate such expansion and transfer the functions given such institute elsewhere in the Service upon a finding by the [Surgeon General] *Secretary* that such expansion is no longer necessary. In the case of any such expansion of an existing institute, the [Surgeon General] *Secretary* may change the title thereof so as to reflect its new functions.

ESTABLISHMENT OF NATIONAL ADVISORY COUNCILS

SEC. 432. [289b] (a) The [Surgeon General is also authorized with the approval of the Secretary] *Secretary is authorized* to establish additional national advisory councils or committees to advise, consult with, and make recommendations to the [Surgeon General] *Secretary* on matters relating to the activities of any institute established under subsection (b) of section 431, or relating to the conduct and support of research and training in such disease or group of diseases (except a disease or group of diseases for which an institute is established under any provision of this title other than section 431(b)) as he may designate. Any such council, and each of the two councils or committees established under section 431(a), shall consist of the [Surgeon General,] *Secretary,* who shall be chairman, the chief medical officer of the Veterans Administra-

tion or his representative and a medical officer designated by the Secretary of Defense, who shall be ex officio members, and of twelve members appointed without regard to the civil service laws by the [Surgeon General with the approval of the] Secretary. The twelve appointed members shall be leaders in the field of fundamental sciences, medical sciences, education, or public affairs, and six of such twelve shall be selected from leading medical or scientific authorities who are outstanding in the study, diagnosis, or treatment of the disease or diseases to which the activities of the institute are directed. Each appointed member of the council shall hold office for a term of four years except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed for the remainder of such term and except that, of the members first appointed, three shall hold office for a term of three years, three shall hold office for a term of two years, and three shall hold office for a term of one year, as designated by the [Surgeon General] *Secretary* at the time of appointment. None of such twelve members shall be eligible for reappointment until a year has elapsed since the end of his preceding term.

(b) In lieu of appointment of an additional advisory council or committee upon the establishment pursuant to subsection (b) of section 431 of an additional institute or upon expansion pursuant to such subsection of the functions of an institute, the [Surgeon General] *Secretary* may expand the functions of an advisory council or committee, established under section 431(a) of any other provisions of this Act so as to include functions with respect to the particular disease or diseases to which the activities of the additional institute or the expanded activities of the existing institute are directed. In the case of any such expansion of an existing council or committee, the membership thereof representing persons outstanding in activities with which the council or committee is concerned may be changed or increased so as to include some persons outstanding in the new activities. Any new council or committee established under subsection (a) of this section or any expansion of an existing council or committee under this subsection may be terminated by the [Surgeon General] *Secretary* at, before, or after the termination of the new institute or expansion of the existing institute which occasioned such new council or committee or expansion of an existing council or committee. In the case of any such expansion of an existing council or committee, the [Surgeon General] *Secretary* may change the title thereto so as to reflect its new functions.

FUNCTIONS

SEC. 433. [289c] (a) Where an institute has been established under this part, the [Surgeon General] *Secretary* shall carry out the purposes of section 301 with respect to the conduct and support of research relating to the disease or diseases to which the activities of the institute are directed, through such institute and in cooperation with the national advisory council or committee established or expanded by reason of the establishment of such institute. The provisions of this subsection shall also be applicable to any in-

stitute established by any other provision of this Act to the extent that such institute does not already have the authority conferred by this subsection.

(b) Upon the appointment of a national advisory council or committee for an institute established under this part or the expansion of an existing institute pursuant to this part, such council or committee shall assume the duties, functions, and powers of the National Advisory Health Council with respect to grants-in-aid for research and training projects relating to the disease or diseases to which the activities of the institute are directed.

NATIONAL INSTITUTE OF [ARTHRITIS, DIABETES,] *DIABETES* AND DIGESTIVE AND KIDNEY DISEASES

SEC. 434. [289c-1] (a) The Research Institute on [Arthritis, Rheumatism, and] Metabolic Diseases established under section 431(a) is designated the "National Institue of [Arthritis, Diabetes,] *Diabetes* and Digestive and Kidney Diseases", and the Advisory Council established under section 432 to advise the Secretary with respect to the activities of the Institute is designated the "National [Arthritis, Diabetes,] *Diabetes* and Digestive and Kidney Diseases Advisory Council".

(b) In the National Institute of [Arthritis, Diabetes,] *Diabetes* and Digestive and Kidney Diseases (hereinafter referred to in this section as the "Institute") there shall be [an Associate Director for Arthritis and Musculoskeletal and Skin Diseases,] an Associate Director for Diabetes, Endocrinology, and Metabolic Diseases, and Associate Director for Digestive Diseases, and an Associate Director for Kidney, Urologic, and Hematologic Diseases who, under the supervision of the Director of the Institute, shall be responsible for—

(1) developing a coordinated plan (including recommendations for expenditures) for each of the national research institutes within the National Institutes of Health with respect to research and training concerning the diseases for which the positions of the Associate Directors were created;

(2) assessing the adequacy of management approaches for the activities within such institutes concerning such diseases and developing improved approaches if needed;

(3) monitoring and reviewing expenditures by such institutes concerning such diseases; and

(4) identifying research opportunities concerning such diseases and recommending ways to utilize such opportunities.

The Director of the Institute shall transmit to the Director of the National Institutes of Health the plans, recommendations, and reviews of the Associate Directors under paragraphs (1) through (4) together with such comments and recommendations as the Director of the institute determines appropriate.

(c) There are established within the Advisory Council of the Institute a subcommittee on diabetes and endocrine and metabolic diseases, [a subcommittee on arthritis and musculoskeletal and skin diseases,] a subcommittee on digestive diseases, and a subcommittee on kidney, urologic, and hematologic diseases. The subcommittees shall be composed of members of the Advisory Council who are outstanding in the diagnosis, prevention, and treatment of the dis-

eases for which the subcommittees are established and members of the Advisory Council who are leaders in the fields of education and public affairs. The subcommittees are authorized to review applications made to the Director for grants for research and training projects relating to the diagnosis, prevention, and treatment of the diseases for which the subcommittees are established and shall recommend to the Advisory Council those applications and contracts that the subcommittees determine will best carry out the purposes of this part. The subcommittees shall also review and evaluate the diabetes and endocrine and metabolic diseases, [arthritis, musculoskeletal and skin diseases,] digestive diseases, and kidney, urologic, and hematologic diseases programs under this part and recommend to the Advisory Council such changes in the administration of such programs as the subcommittees determine are necessary.

(d) The Director of the Institute, acting through [the Associate Director for Arthritis and Musculoskeletal and Skin Diseases,] the Associate Director for Kidney, Urologic, and Hematologic Diseases, the Associate Director for Digestive Diseases, and the Associate Director for Diabetes, Endocrinolgy, and Metabolic Diseases, shall—

(1) carry out programs of support for research and training (other than training for which National Research Service Awards may be made under section 472) in the diagnosis, prevention, and treatment of [arthritis, musculoskeletal and skin diseases,] digestive diseases, diabetes mellitus, and endocrine and metabolic, kidney, urologic, and hematologic diseases, including support for training in medical schools, graduate clinical training, graduate training in epidemiology, epidemiology studies, clinical trials, and interdisciplinary research programs; and

(2) establish programs of evaluation, planning, and dissemination of knowledge related to such research and training.

(e) The Director of the Institute shall, as soon as practicable, but not later than sixty days, after the end of each fiscal year, prepare, in consultation with the National Advisory Council, and submit to the President and to the Congress an annual report. The annual report shall include a description of the Institute's activities—

[(a) under the current Arthritis Plan prepared under the National Arthritis act of 1974,]

(1) [(2)] under the current diabetes plan prepared under the National Diabetes Mellitus Research and Education Act, and

(2)[(3)] under the current digestive diseases plan prepared under the Arthritis, Diabetes, and Digestive Diseases Amendments of 1976.

DIABETES RESEARCH AND TRAINING CENTERS; DIABETES DATA GROUP AND CLEARINGHOUSE

SEC. 435. [289c-2] (a) Consistent with applicable recommendations of the current diabetes plan under the National Diabetes Mellitus Research and Education Act, the Secretary shall provide for the development, or substantial expansion, of centers for research and training in diabetes mellitus and related endocrine and metabolic disorders. Each center developed or expanded under this

section shall (1) utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research and training qualifications as may be prescribed by the Secretary; and (2) conduct (A) research in the diagnosis and treatment of diabetes mellitus and related endocrine and metabolic disorders and the complications resulting from such disease or disorders, (B) training programs for physicians and allied health personnel in current methods of diagnosis and treatment of such disease, disorders, and complications, and (C) information programs for physicians and allied health personnel who provide primary care for patients with such disease, disorders, or complications. Insofar as practicable, centers developed or expanded under this section shall be located geographically on the basis of population density throughout the United States and in environments with proven research capabilities. A center may use funds provided under this subsection to provide stipends for health professionals enrolled in training programs described in clause (2)(B).

(b) The Secretary shall evaluate on an annual basis the activities of centers developed or expanded under this section and shall report to the Congress (on or before November 30 of each year) the results of his evaluation.

(c)(1) The Secretary, with the Associate Director for Diabetes, Endocrinology, and Metabolic Diseases, shall (A) establish the Diabetes Data Group and the Diabetes Information Clearinghouse, and (B) through such entities, establish the diabetes data system for the collection, storage, analysis, retrieval, and dissemination of data concerning diabetes, including, where possible, data involving general populations for the purpose of detecting individuals with a risk of developing diabetes.

(2) There is authorized to be appropriated to carry out this subsection $2,000,000 for the fiscal year ending September 30, 1981; $2,000,000 for the fiscal year ending September 30, 1982; [and] $2,000,000 for the fiscal year ending September 30, 1983; *$2,000,000 for the fiscal year ending September 30, 1984; $2,000,000 for the fiscal year ending September 30, 1985; and $2,000,000 for the fiscal year ending September 30, 1986.*

(d) There are authorized to be appropriated to carry out this section (other than subsection (c)) $8,000,000 for fiscal year ending June 30, 1975, $12,000,000 for fiscal year ending June 30, 1976, $20,000,000 for fiscal year ending June 30, 1977, $12,000,000 for the fiscal year ending September 30, 1978, $20,000,000 for the fiscal year ending September 30, 1979, $20,000,000 for fiscal year ending September 30, 1980, $14,000,000 for fiscal year ending September 30, 1981, $17,000,000 for fiscal year ending September 30, 1982, [and] $20,000,000 for fiscal year ending September 30, 1983, *$20,000,000 for fiscal year ending September 30, 1984, $20,000,000 for fiscal year ending September 30, 1985, and $20,000,000 for fiscal year ending September 30, 1986.*

INTERAGENCY COORDINATING COMMITTEES

SEC. 436. [289c-3] (a) For the purpose of—

(1) better coordinating the research activities of all the national research institutes relating to [arthritis, diabetes mellitus,] *diabetes mellitus* and digestive diseases; and

(2) coordinating those aspects of all Federal health programs and activities relating to such diseases to assure the adequacy and technical soundness of such programs and activities and to provide for the full communication and exchange of information necessary to maintain adequate coordination of such programs and activities,

the Secretary shall establish [an Arthritis Interagency Coordinating Committee,] a Diabetes Mellitus Interagency Coordinating Committee (hereinafter in this section individually referred to as a "Committee").

(b) Each Committee shall be composed of the Directors (or their designees) of each of the national research institutes and divisions involved in research regarding the diseases with respect to which the Committee is established, the Associate Director of the National Institute of [Arthritis, Diabetes,] *Diabetes* and Digestive and Kidney Diseases for the diseases for which the Committee is established, and chief medical director (or the director's designee) of the Veterans' Administration, and a medical officer designated by the Department of Defense, and shall include representation from all other Federal departments and agencies whose programs involve health functions or responsibilities relevant to such diseases, as determined by the Secretary. Each Committee shall be chaired by the Director of the National Institutes of Health (or the Director's designee). Each Committee shall meet at the call of the chairman, but not less often than four times a year.

(c) Each Committee shall prepare an annual report for—

(1) the Secretary,

(2) The Director of the National Institutes of Health, and

(3) the Advisory Board established under section 437 for the disease for which the Committee was established.

detailing the work of the Committee in the fiscal year for which the report was prepared in carrying out the coordinating activities described in paragraphs (1) and (2) of subsection (a). Such report shall be submitted not later than the sixtieth day after the end of each fiscal year.

[DIABETES, ARTHRITIS, AND DIGESTIVE DISEASES ADVISORY BOARDS]

DIABETES, KIDNEY AND UROLOGIC DISEASES, AND DIGESTIVE DISEASES ADVISORY BOARDS

SEC. 437. [289c–4] (a) The Secretary shall establish [the National Arthritis Advisory Board,] the National Diabetes Advisory Board, *the National Kidney and Urologic Diseases Advisory Board,* and the National Digestive Diseases Advisory Board (hereinafter in this section individually referred to as an "Advisory Board").

(b) Each Advisory Board shall be composed of eighteen appointed members and nonvoting, ex officio members as follows:

(1) The Secretary shall appoint—

(A) twelve members from individuals who are scientists, physicians, and other health professionals, who are not of-

ficers or employees of the United States, and who represent the specialities and disciplines relevant to the diseases with respect to which the Advisory Board is established; and

(B) six members from the general public who are knowledgeable with respect to such diseases, including at least one member who is a person who suffers from the disease and one member who is a parent of a person who suffers from the disease.

Of the appointed members, at least five shall by virtue of training or experience be knowledgeable in health education, nursing, data systems, public information, or community program development.

(2) The following shall be ex officio members of each Advisory Board: The Assistant Secretary of Health, the Director of the National Institutes of Health, the Director of the National Institute of [Arthritis, Diabetes,] *Diabetes* and Digestive and Kidney Diseases, the Director of the Center for Disease Control, the chief medical director of the Veterans' Administration, a medical officer designated by the Department of Defense (or the designees of such ex officio members), the Associate Director of the National Institute of [Arthritis, Diabetes,] *Diabetes* and Digestive and Kidney Diseases for the diseases for which the Board is established, and such other officers and employees of the United States as the Secretary deems necessary for the Advisory Board to carry out its functions. In the case of the National Diabetes Advisory Board, the following shall also be ex officio members: The Director of the National Heart, Lung, and Blood Institute, the Director of the National Eye Institute, the Director of the National Institute of Child Health and Human Development, the Administrator of the Health Resources Administration, and the Administrator of the Health Services Administration (or their designees of such ex officio members).

(c) Members of an Advisory Board who are officers or employees of the Federal Government shall serve as members of the Advisory Board without compensation in addition to that received in their regular public employment. Other members of the Board shall receive compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS–18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Board.

(d) The term of office of an appointed member of an Advisory Board is three years, except that no term of office may extend beyond the expiration of the Advisory Board. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has taken office. If a vacancy occurs in an Advisory Board, the Secretary shall make an appoaintment to fill the vacancy not later than ninety days from the date the vacancy occurs. In the case of the National Diabetes Advisory Board [and the National Arthritis Advisory Board] Six of the members of each such Advisory Board whose terms expired

on September 30, 1980, shall be reappointed for a term of three years.

(e) The members of each Advisory Board shall select a chairman from among the appointed members.

(f) The Secretary shall, after consultation with and consideration of the recommendations of an Advisory Board, provide the Advisory board with an executive director and one other professional staff member. In addition, the Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with such additional professional staff members, such clerical staff members, and (through contracts or other arrangements) with such administrative support services and facilities, such information, and such services of consultants, as the Secretary determines are necessary for the Advisory Board to carry out its functions.

(g) Each Advisory Board shall meet at the call of the chairman or upon request of the Director of the National Institute for [Arthritis, Diabetes,] *Diabetes* and Digestive and Kidney Diseases, but not less often than four times a year.

(h) Each Advisory Board shall—

(1) review and evaluate the implementation of the plan referred to in section 434(e) regarding the diseases with respect to which the Advisory Board was established;

(2) periodically update the plan referred to in paragraph (1) to ensure its continuing relevance;

(3) for the purpose of assuring the most effective use and organization of resources respecting such diseases, advise and make recommendations to Congress, the Secretary, the Director of the National Institutes of Health, the Director of the National Institute for [Arthritis, Diabetes,] *Diabetes* and Digestive and Kidney Diseases, and the heads of other appropriate Federal agencies for the implementation of such plan; and

(4) maintain liaison with other advisory bodies related to Federal agencies involved in the implementation of such plan, the Coordinating Committee for such diseases, and with key non-Federal entities involved in activities affecting the control of such diseases.

(i) In carrying out its functions, the Advisory Board may establish subcommittees, convene workshops and conferences, and collect data. Such subcommittees may be composed of Advisory Board members and nonmember consultants with expertise in the particular area addressed by such subcommittees. The subcommittees may hold such meetings as are necessary to enable them to carry out their activities.

(j) Each Advisory Board shall submit to the Secretary and Congress an annual report which—

(1) describes the Advisory Board's activities in the fiscal year for which the report is made;

(2) describes and evaluates the progress made during such year in research, treatment, education, and training with respect to the diseases with respect to which the Advisory Board was established;

(3) summarizes and analyzes expenditures made by the Federal Government for activities respecting such diseases in the fiscal year for which the report is made; and

(4) contains the Advisory Board's recommendations, if any, for changes in the plan referred to in subsection (h)(1).

(k) For each Advisory Board there is authorized to be appropriated $300,000 for the fiscal year ending September 30, 1981; $300,000 for the fiscal year ending September 30, 1982; [and] $300,000 for the fiscal year ending September 30, 1983*; $300,000 for the fiscal year ending September 30, 1984; $300,000 for the fiscal year ending September 30, 1985; and $300,000 for the fiscal year ending September 30, 1986.*

(l) Each Advisory Board shall expire on September 30, [1983] *1986.*

[ARTHRITIS DEMONSTRATION PROJECTS AND DATA SYSTEM]

[SEC. 438. [289c-5] (a) The Secretary may make grants to public and nonrofit entities to establish and support projects for the development and demonstration of methods for arthritis, screening, detection, and referral and for dissemination of these methods to the health and allied health professions. Activities under such projects shall be coordinated with (1) Federal, State, local, and regional health agencies, (2) centers assisted under section 439, and (3) the data system established under subsection (c).

[(b) Projects under this section shall include programs which—

(1) emphasize the development and demonstration of new and improved methods of screening and early detection, referral, and diagnosis of individuals with a risk of developing arthritis, asymptomatic arthritis, or symptomatic arthritis;

[(2) emphasize the development and demonstration of new and improved methods for patient referral from local hospitals and physicians to appropriate centers for early diagnosis and treatment;

[(3) emphasize the development and demonstration of new and improved means of standardizing patient data and recordkeeping;

[(4) emphasize the development and demonstration of new and improved methods of dissemination of knowledge about the projects and methods referred to in the preceding paragraphs of this subsection to health and allied health professionals;

[(5) emphasize the development and demonstration of new and improved methods for the dissemination to the general public of information—

[(A) on the importance of early detection of arthritis, of seeking prompt treatment, and of following an appropriate regimen; and

[(B) to discourage the promotion and use of unapproved and ineffective diagnostic, preventive, treatment, and control methods for arthritis and unapproved and ineffective drugs and devices for arthritis; and

[(6) projects for the investigation into the epidemiology of all forms and aspects of arthritis, including investigations into the social, environmental, behavioral, nutritional, and genetic determinants and influences involved in the epidemiology of arthritis.

[(c)(1) As soon as practical after the date of enactment of this section the Secretary, through the Assistant Secretary for Health, shall establish the Arthritis Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with asymptomatic and symptomatic types of arthritis, including where possible, data involving general populations for the purpose of detection of individuals with a risk of developing arthritis.

(2) The Secretary shall provide for standardization of patient data and recordkeeping for the collection, storage, analysis, retrieval, and dissemination of such data in cooperation with projects under this section and centers assisted under section 439, and other persons engaged in arthritis programs.

[(d)(1) There are authorized to be appropriated to carry out this section $2,000,000 for fiscal year ending June 30, 1975, $3,000,000 for fiscal year ending June 30, 1976, and $4,000,000 for fiscal year ending June 30, 1977.

[(2) There are authorized to be appropriated to carry out subsections (a) and (b) $3,000,000 for the fiscal year ending September 30, 1978, $4,000,000 for the fiscal year ending September 30, 1979, and $5,000,000 for the fiscal year ending September 30, 1980, and for each of the next 3 fiscal years.

[(3) There are authorized to be appropriated to carry out subsection (c) $1,000,000 for the fiscal year ending September 30, 1978, $1,250,000 for the fiscal year ending September 30, 1979, and $1,500,000 for the fiscal year ending September 30, 1980, and for each of the next 3 fiscal years.]

[MULTIPURPOSE ARTHRITIS CENTERS]

[SEC. 439. [289c–5] (a) The Secretary may, after consultation with the National Advisory Council established under section 434(a) and consistent with the Arthritis Plan developed pursuant to the National Arthritis Act of 1974, provide for the development, modernization, and operation (including staffing, and other operating costs such as the costs of patient care required for research) of new and existing centers for arthritis research, screening, detection, diagnosis, prevention, control, and treatment, for education related to arthritis, and for the rehabilitation of individuals who suffer from arthritis. For purposes of this section, the term "modernization" means the alteration, remodeling, improvement, expansion, and repair of existing buildings and the provision of equipment for such buildings to the extent necessary to make them suitable for use as centers described in the preceding sentence.

[(b) Each center assisted under this section shall—

[(1)(A) use the facilities of a single institution or a consortium of cooperating institutions, and (B) meet such qualifications as may be prescribed by the Secretary; and

[(2) conduct—

[(A) basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of arthritis and complications resulting from arthritis, including research into implantable biomaterials and biomechanical and other orthopedic procedures and in the development of other diagnostic and treatment methods;

[(B) training programs for physicians and other health and allied professionals in current methods of diagnosis, screening and early detection, prevention, control, and treatment of arthritis, and in research in arthritis;

[(C) information and continuing education programs for physicians and other health and allied health professionals who provide care for patients with arthritis; and

[(D) programs for the dissemination to the general public of information—

[(i) on the importance of early detection of arthritis, of seeking prompt treatment, and of following an appropriate regimen; and

[(ii) to discourage the promotion and use of unapproved and ineffective diagnostic, preventive, treatment, and control methods and unapproved and ineffective drugs and devices.

A center may use funds provided under this subsection to provide stipends for health professionals enrolled in training programs described in paragraph (2)(B).

[(c) Each center assisted under this section may conduct programs to—

[(1) develop new and improved methods of screening and early detection, referral, and diagnosis or individuals with a risk of developing arthritis, asymptomatic arthritis, or symptomatic arthritis,

[(2) disseminate the results of research, screening, and other activities, and develop means of standardizing patient data and recordkeeping, and

[(3) develop community consultative services to facilitate the referral of patients to centers for treatment.

[(d) The Secretary shall, insofar as practicable, provide for an equitable geographical distribution of centers assisted under this section. The Secretary shall give appropriate consideration to the need for centers especially suited to meeting the needs of children affected by arthritis.

[(e) The Secretary shall evaluate on an annual basis the activities of centers receiving support under this section and shall report to the appropriate committees of Congress the results of his evaluations on or before November 30 of each year.

[(f) For purposes of this section, there are authorized to be appropriated $11,000,000 for the fiscal year ending June 30, 1975, $8,000,000 for the fiscal year ending June 30, 1976, $20,000,000 for the fiscal year ending June 30, 1977, $18,700,000 for the fiscal year ending September 30, 1978, $19,000,000 for the fiscal year ending September 30, 1979, $20,000,000 for the fiscal year ending September 30, 1980, $14,000,000 for the fiscal year ending September 30, 1981, $17,000,000 for the fiscal year ending September 30, 1982, and $20,000,000 for the fiscal year ending September 30, 1983.]

DIGESTIVE DISEASES RESEARCH CENTERS; DIGESTIVE DISEASES INFORMATION CLEARINGHOUSE AND DATA SYSTEM

SEC. 439. (a) Consistent with applicable recommendations of the National Digestive Diseases Advisory Board, the Director of the National Institute of Diabetes and Digestive and Kidney Diseases (hereafter in this section referred to as the "Director") shall provide for the development or substantial expansion of centers for research concerning digestive diseases and related functional, congenital, and metabolic disorders, and for research concerning the normal development of the digestive tract. Each center developed or expanded under this section—

(1) shall utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research qualifications as may be prescribed by the Director;

(2) shall develop and conduct basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of digestive diseases and related functional, congenital, or metabolic complications resulting from such diseases;

(3) shall encourage research concerning, and programs for—

(A) the provision of information to patients with such diseases and complications, the families of such patients, physicians and other individuals who care for such patients, and the general public;

(B) cost effective and preventive patient care; and

(C) training physicians and scientists in research on such diseases and complications: and

(4) may perform research and participate in epidemiological studies and the collection of data relevant to digestive diseases and related functional, congential, or metabolic complications resulting from such diseases in order to disseminate such data and the findings of such research and studies to health care professionals and the public.

(b) (1) Insofar as practicable, centers developed or expanded under subsection (a) should be geographically distributed throughout the United States and distributed among institutions with proven research capabilities.

(2) Support of a center under this section may be for a period of not in excess of five years. Such period may be extended by the Director for one or more additional periods of not more than five years if the operations of such center have been reviewed by an appropriate scientific review group established by the Director and such scientific review group has recommended to the Director that support of such center under this section should be extended.

(3) To carry out this subsection and subsection (a), there are authorized to be appropriated $8,000,000 for the fiscal year ending septemberr 30, 1984, $9,000,000 for the fiscal year ending September 30, 1985, and $10,000,000 for the fiscal year ending September 30, 1986.

(c)(1) The Director shall (A) establish the National Digestive Diseases Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with digestive diseases, including, where possible, data involving general populations for the purpose of detection of individuals with a risk of

developing digestive diseases, and (B) establish the National Digestive Diseases Information Clearinghouse to facilitate and enhance knowledge and understanding of digestive diseases by health care professionals, patients, and the public through the effective dissemination of information.

(2) To carry out this subsection, there are authorized to be appropriated $1,000,000 for the fiscal year ending September 30, 1984, $1,100,000 for the fiscal year ending September 30, 1985, and $1,200,000 for the fiscal year ending September 30, 1986.

INFORMATION AND EDUCATION CENTER FOR DIGESTIVE DISEASES

SEC. 440. [289c-7] The Secretary, acting through the Director of the National Institute of [Arthritis, Diabetes,] *Diabetes* and Digestive and Kidney Diseases, shall establish an information and education center for digestive diseases (1) to identify, collect, analyze, and disseminate information respecting the diseases, and (2) to serve as a national educational resource for patients with such diseases and their families, physicians, and other health professionals.

COORDINATING COMMITTEE FOR DIGESTIVE DISEASES

SEC. 440A. [289c-8] (a) The Secretary shall establish a Coordinating Committee for Digestive Diseases (hereafter in this section referred to as the "Committee") to be composed of the Directors (or their designated representatives) of each of the Institutes of the National Institutes of Health involved in digestive disease research; and the head (of his designated representative) of the Alcohol, Drug Abuse and Mental Health Administration, the National Institute of Occupational Safety and Health, the Food and Drug Administraion, the Department of Medicine and Surgery of the Veterans' Administration, the Center for Disease Control, the Department of Defense, the Department of Agriculture, the Health Services Administration, the Health Resources Administration, the Social Security Administration, and the Institute of Medicine of the National Academy of Sciences. The Committee shall be chaired by the Director of the National Institute of [Arthritis, Metabolism,] *Diabetes* and Digestive Diseases and the Associate Director for Digestive Diseases and Nutrition of that Institute shall serve as vice chairman. The Committee shall meet at the call of the Chairman, but not less often than three times a year.

(b) The Committee shall be responsible for the coordination of the activities of the entities represented on the Committee respecting digestive diseases. The Committee shall submit to the Secretary an annual report detailing the manner in which the Committee has coordinated such activities.

PART E—INSTITUTES OF CHILD HEALTH AND HUMAN DEVELOPMENT AND OF GENERAL MEDICAL SCIENCES

ESTABLISHMENT OF INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

SEC. 441. [298d] (a) The Surgeon General is authorized, with the approval of the Secretary, to establish in the Public Health Service

the National Institute of Child Health and Human Development for the conduct and support of research and training relating to *mental retardation,* maternal health, child health, and human development, including research and training in the special health problems and requirements of mothers and children and in the basic sciences relating to the process of human growth and development, including prenatal development.

(b) The Secretary shall carry out through the National Institute of Child Health and Human Development the purposes of section 301 with respect to the conduct and support of research which specifically relates to sudden infant death syndrome.

(c) The Secretary, through the Director of the National Institute of Child Health and Human Development, shall make grants to centers which—

(1) were constructed under the part D of title VII of this Act that was added to this Act by section 121 of Public Law 88-164; and

(2) are engaged in research and related activities with respect to the causes, prevention, and treatment of mental retardation.

ESTABLISHMENT OF INSTITUTE OF GENERAL MEDICAL SCIENCES

SEC. 442. [289e] The [Surgeon General is authorized, with the approval of the Secretary,] *Secretary is authorized* to establish in the Public Health Service an institute for the conduct and support of research and training in the general or basic medical sciences and related natural or behavioral sciences which have significance for two or more other institutes, or are outside the general area of responsibility of any other institute, established under or by this Act.

ESTABLISHMENT OF ADVISORY COUNCILS

SEC. 443. [289f] (a) The [Surgeon General is authorized, with the approval of the Secretary.] *Secretary is authorized to* establish an advisory council or committee to advise, consult with, and make recommendations to the [Surgeon General] *Secretary* on matters relating to the activities of the institute established under section 441. He may also, with such approval, establish such a council or committee with respect to the activities of the institute established under section 442.

(b) The provisions relating to the composition, terms of office of members, and reappointment of members of advisory councils or committees under section 432(a) shall be applicable to any council or committee established under this section, except that, in lieu of the requirement in such section that six of the members be outstanding in the study, diagnosis, or treatment of a disease or diseases, six of such members shall be selected from leading medical or scientific authorities who are outstanding in the field or research or training with respect to which the council or committee is being established, and except that the [Surgeon General with the approval of the Secretary] *Secretary* May include on any such council or committee established under this section such additional ex officio members as he deems necessary in the light of the functions of the institute with respect to which it is established.

(c) Upon appointment of any such council or committee, it shall assume all or such part as the [Surgeon General may, with the approval of the Secretary,] *Secretary may* specify of the duties, functions, and powers of the National Advisory Health Council relating to the research or training projects with which such council or committee established under this part is concerned and such portion as the [Surgeon General may specify (with such approval)] *Secretary may specify* of the duties, functions, and powers of any other advisory council or committee established under this Act relating to such projects.

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PRESERVATION OF EXISTING AUTHORITY

SEC. 445. [289h] Nothing in this part shall be construed as affecting the authority of the Secretary under section 2 of the Act of April 9, 1912 (42 U.S.C. 192), or title V of the Social Security Act (42 U.S.C., ch. 7, subch. V), or as affecting the authority of the [Surgeon General] *Secretary* to utilize institutes established under other provisions of this Act for research or training activities relating to maternal health, child health, and human development or to the general medical sciences and related sciences.

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PART H—NATIONAL INSTITUTE ON AGING

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FUNCTIONS

SEC 463. [289k-4] (a) The secretary (1) shall, through the Institute, carry out the purposes of section 301 with respect to research investigations, experiments demonstrations, and studies related to the aging process and the diseases and other special problems and needs of the aged, except that the Secretary shall determine the area in which and the extent to which he will carry out such activities in furtherance of the purposes of section 301 through the Institute or another institute established by or under other provisions of this Act, or both of them, when both such institutes have functions with respect to the same subject matter and (2) shall be responsible for coordinating such activities so as to avoid unproductive and unnecessary overlap and duplication of such functions. The Secretary may also provide training and instruction and establish traineeships and fellowships, in the Institute and elsewhere, in matters relating to study and investigation of the aging process and the diseases and other special problems and needs of the aged. The Secretary may provide trainees and fellows participating in such training and instruction or in such traineeships and fellowships with such stipends and allowances (including travel and subsistence expenses and dependency allowances) as he deems necessary, and, in addition, provide for such training, instruction, traineeships, fellowships through grants to public or other nonprofit institutions. In carrying out his health manpower training responsibilities under this Act or any other Act, the Secretary shall take

appropriate steps to insure the education and training of adequate numbers of allied health, nursing, and paramedical personnel in the field of health care for the aged.

(b) The Secretary shall, through the Institute, conduct scientific studies to measure the impact on the biological, medical, and psychological aspects of aging of all programs and activities assisted or conducted by the Department of [Health Education, and Welfare]. *Health, and Human Services.*

(c) The Secretary, through the Institute, shall carry out public information and education programs designed to disseminate as widely as possible the findings of Institute-sponsored and other relevant aging research and studies and other information about the process aging which may assist elderly and near-elderly persons in dealing with, and all Americans in understanding, the problems and processes associated with growing older.

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PART I—GENERAL PROVISIONS

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NATIONAL RESEARCH SERVICE AWARDS

SEC. 472. [289*l*-1] (a)(1) The Secretary shall—

(A) provide National Research Service Awards for—

(i) biomedical and behavioral research at the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration or under programs administered by the Division of Nursing of the Health Resources Administration, in matters relating to the cause, diagnosis, prevention, and treatment of the diseases or other health problems to which the activities of the Institutes and Administration or Division of Nursing are directed.

(ii) training at the Institutes and Administration of individuals to undertake such research,

(iii) biomedical and behavioral research at public institutions and at nonprofit private institutions, and

(iv) pre- and post-doctoral training at such public and private institutions of individuals to undertake biomedical and behavioral research; and

(B) make grants to public institutions and to nonprofit private institutions to enable such institutions to make to individuals selected by them National Research Service Awards for research (and training to undertake biomedical and behavioral research and the research described in subparagraphs (A)(vi)) in the matters described in subparagraph (A)(i).

A reference in this subsection to the National Institutes of Health or the Alcohol, Drug Abuse, and Mental Health Administration shall be considered to include the institutes, divisions, and bureaus included in the Institutes or under the Administration, as the case may be

(2) National Research Service Awards may not be used to support residences.

(3) In awarding National Research Service Awards under this section, the Secretary shall take account of the Nation's overall need for biomedical research personnel by giving special consideration to physicians who agree to undertake a minimum of two years of biomedical research.

(b)(1) No national Research Service Award may be made by the Secretary to any individual unless—

(A) the individual has submitted to the Secretary an application therefor and the Secretary has approved the application;

(B) the individual provides, in such form and manner as the Secretary shall by regulation prescribe, assurances satisfactory to the Secretary that the individual will meet the service requirement of subsection (c)(1); and

(C) in the case of a National Research Service Award for a purpose described in subsection (a)(1)(A)(iii), the individual has been sponsored (in such manner as the Secretary may by regulation require) by the institution at which the research or training under the Award will be conducted.

An application for an Award shall be in such form, submitted in such manner, and contain such information, as the Secretary may by regulation prescribe.

(2) the making of grants under subsection (a)(1)(B) for National Research Service Awards shall be subject to review and approval by the appropriate advisory councils within the Department of Health and Human Services (A) whose activities relate to the research or training under the Awards, or (B) at which such research or training will be conducted.

(3) No grant may be made under subsection (a)(1)(B) unless an application therefor has been submitted to and approved by the Secretary. Such application shall be in such form, submitted in such manner, and contain such information, as the Secretary may by regulation prescribe. Subject to the provisions of this section other than paragraph (1) of this subsection, National Research Service awards made under a grant under subsection (a)(1)(B) shall be made in accordance with such regulations as the Secretary shall prescribe.

(4) The period of any National Research Service Award made to any individual under subsection (a) may not exceed—

(A) five years in the aggregate for predoctoral training, and

(B) three years in the aggregate for postdoctoral training,

unless the Secretary for good cause shown waives the application of such limit to such individual.

(5) National Research Service Awards shall provide for such stipends, tuition, fees, and allowances (including travel and subsistence expenses and depenency allowances), adjusted periodically to reflect increases in the cost of living for the recipients of the Awards as the Secretary may deem necessary. A National Research Service Award made to an individual for research of research training at a non-Federal public or nonprofit private institution shall also provide for payments to be made to the institution for the cost of support services (including the cost of faculty salaries, supplies, equipment, general research support, and related items) provided such individual by such institution. The amount of any such payments to any institution shall be determined by the

Secretary and shall bear a direct relationship to the reasonable costs of the institution for establishing and maintaining the quality of its biomedical and behavioral research and training programs.

[(c)(1) Each individual who is awarded a National Research Service Award (other than an individual who is a prebaccalaureate student who is awarded a National Research Service Award for research training) shall, in accordance with paragraph (3), engage in health research or teaching or any combination thereof which is in accordance with the usual patterns of academic employment, for a period computed in accordance with paragraph (2).

[(2) For each month for which an individual receives a National Research Service Award which is made for a period in excess of twelve months, such individual shall engage in one month of health research or teaching or any combination thereof which is in accordance with the usual patterns of academic employment.

(3) The requirement of paragraph (1) shall be complied with by any individual to whom it applies within such reasonable period of time, after the completion of such individual's Award, as the Secretary shall be regulation prescribe. The Secretary shall by regulation prescribe the type of research and teaching in which an individual may engage to comply with such requirement and such other requirements respecting research and teaching as the Secretary considers appropriate.

[(4)(A) If any individual to whom the requirement of paragraph (1) is applicable fails, within the period prescribed by paragraph (3), to comply with such requirements, the United States shall be entitled to recover from such individual an amount determined in accordance with the formula—

$$A = \phi(t—s/t)$$

in which "A" is the amount the United States is entitled to recover; "ϕ" is the sum of the total amount paid under one or more National Research Service Awards to such individual; "t" is the total number of months in such individual's service obligation; and "s" is the number of months of such obligation served by him in accordance with paragraphs (1) and (2) of this subsection.

[(B) Any amount which the United States is entitled to recover under subparagraph (A) shall, within the three-year period beginning on the date the United States becomes entitled to recover such amount, be paid to the United States. Until any amount due the United States under subparagraph (A) on account of any National Research Service Award is paid, there shall accrue to the United States interest on such amount at a rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date the United States becomes entitled to such amount.

[(5)(A) Any obligation of any individual under paragraph (3) shall be canceled upon the death of such individual.

[(B) The Secretary shall by regulation provide for the waiver or suspension of any such obligation applicable to any individual whenever compliance by such individual is impossible or would involve substantial hardship to such individual and if enforcement of

such obligation with respect to any individual would be against equity and good conscience.]

[[d]]*(c)* There are authorized to be appropriated to make payments under National Research Service Awards and under grants for such Awards $207,947,000 for this fiscal year ending June 30, 1975, $165,000,000 for fiscal year 1976, $185,000,000 for the fiscal year ending September 30, 1977, $161,390,000 for the fiscal year ending September 30, 1978, $197,500,000 for the fiscal year ending September 30, 1979, $210,000,000 for the fiscal year ending September 30, 1980, $222,500,000 for the fiscal year ending September 30, 1981 $182,000,000 for the fiscal year ending September 30, 1982, [and] $195,000,000 for the fiscal year ending September 30, 1983, *$195,048,000 for the fiscal year ending September 30, 1984, $204,800,400 for the fiscal year ending September 30, 1985, and $215,040,420 for the fiscal year ending September 30, 1986.*

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PEER REVIEW OF GRANT APPLICATIONS AND CONTRACT PROJECTS

SEC. 475. [289*l*-4] (a) The Secretary, after consultation with the Director of the National Institutes of Health, and where appropriate, the Directors of the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse and the head of the Division of Nursing of the Health Resources Administration (or the successor to either such entity), shall by regulation require appropriate scientific peer review of—

(1) applications made after the effective date of such regulations for grants under this Act for biomedical and behavioral research (including reseach under programs of such Division of Nursing); and

(2) biomedical and behavioral research and development contract projects to be administered after such effective date through an institute established under this title, the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse, or the Division or Nursing of the Health Resources Administration (or the successor to either such entity).

(b) Regulations promulgated under subsection (as) shall, to the extent practical, require that the review of grant applications required by the regulations be conducted—

(1) in a manner consistent with the system for scientific peer review applicable on the date of the enactment of this section to applications for grants under this Act for biomedical and behavioral research, and

(2) by peer review groups performing such review on or before such date.

(c) the members of any peer review group established under such regulations shall be individuals who by virtue of their training or experience are eminently qualified to perform the review functions of the group and not more than one-fourth of the members of any peer review group established under such regulations shall be officers or employees of the United States.

(d) By January 1, 1984 and annually thereafter, the Secretary shall prepare and transmit to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives a report concerning any activities undertaken in the preceding fiscal year to improve the grant, contracting, accountability, and peer review procedures of the National Institutes of Health, including the National Cancer Institute.

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INVESTIGATIONS

SEC. 480. The Director of each national research institute in the National Institutes of Health shall notify the National Advisory Council for such research institute of the status of any investigation concerning any recipient of a grant or contract from such research institute, unless the office or unit of the national research institute or of the National Institutes of Health which is conducting the investigation advises the Director of such national research institute that disclosure to the Council under this section will jeopardize the investigation.

RESEARCH FOR PUBLIC HEALTH EMERGENCIES

SEC. 481. (a) If the Secretary determines, after consultation with the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, or the Director of the Centers for Disease Control, that a disease or disorder constitutes a public health emergency, the Secretary, acting through the Director of the National Institutes of Health—

(1) shall expedite the review by the National Cancer Advisory Board under section 407 (b) or by any of the advisory councils of the other national research institutes under section 418, 424, 433, 443, 452, or 462, as the case may be, and by peer review groups under sections 405 and 475, of applications for grants for research on such disease or disorder or proposals for contracts for such research;

(2) shall exercise the authority in section 3709 of the Revised Statutes respecting public exigencies to waive the advertising requirements of such section in the case of proposals for contracts for such research; and

(3) may provide administrative supplemental increases in existing grants and contracts to support new research relevant to such disease or disorder.

The amount of an increase in a grant or contract provided under paragraph (3) may not exceed one-half the original amount of the grant or contract.

(b) Not later than ninety days after the expiration of a fiscal year, the Secretary shall report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate on actions taken under subsection (a) in such fiscal year.

PART J—NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

ESTABLISHMENT OF INSTITUTE

SEC. 491. There is established in the Public Health Service a National Institute of Arthritis and Musculosketetal and Skin Diseases (hereinafter in this part referred to as the 'Institute'). The Institute shall be headed by a Director.

PURPOSE OF THE INSTITUTE

SEC. 492. (a) The purpose of the Institute is the conduct and support of research and training, the dissemination of health information, and related programs with respect to arthritis and musculoskeletal and skin diseases, including sports-related disorders.

(b)(1) Within one hundred and eighty days after the effective date of this part, the Director of the Institute, with the advice of the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council established pursuant to section 495 (hereafter referred to in this part as the Advisory Council), shall prepare and transmit to the Director of the National Institutes of Health a plan for a national arthritis and musculoskeletal diseases of the Institute respecting arthritis and musculoskeletal diseases. The program shall be coordinated with the other national research institutes of the National Institutes of Health to the extent that such institutes have responsibilities respecting arthritis and musculoskeletal diseases, and shall, at least, provide for—

(A) investigation into the epidemiology, etiology, and prevention of all forms of arthritis and musculoskeletal diseases, including sports-related disorders, primarily through the support of basic research in such areas as immunology, genetics, biochemistry, microbiology, physiology, bioengineering, and any other scientific discipline which can contribute important knowledge to the treatment and understanding of arthritis and musculoskeletal diseases;

(B) research into the development, trial, and evaluation of techniques, drugs, and devices used in the diagnosis, treatment, including medical rehabilitation and prevention of arthritis and musculoskeletal diseases;

(C) research on the refinement, development, and evaluation of technological devices that will replace or be a substitute for damaged bone, muscle, and joints and other supporting structures, and

(D) the establishment of mechanisms to monitor the causes of athletic injuries and identify ways of preventing such injuries on scholastic athletic fields.

(2) The plan transmitted pursuant to paragraph (1) shall include such comments and recommendations as the Director of the Institute determines appropriate.

(3) The Director of the Institute shall carry out the national arthritis and musculoskeletal diseases program in accordance with the plan prepared under paragraph (1). The Director of the Institute shall periodically review and revise such plan, shall transmit any revisions of such plan to the Director of the National Institutes of

Health, and shall carry out the national arthritis and musculoskeletal diseases program in accordance with such revisions.

(c) Within one hundred and eighty days after the effective date of this part, and annually thereafter, the Director of the Institute shall, with the advice of the Advisory Council, prepare and transmit to the Director of the National Institutes of Health and report [illegible] aluates the skin diseases programs carried out by the national research institutes on the effective date of this part and which contains such comments and recommendations concerning such programs as the Director of the Institute determines appropriate.

(d) The Director of the Institute shall—

(1) carry out programs of support for research and training (other than training for which National Research Service Awards may be made under section 472) in the diagnosis, prevention, and treatment of arthritis and musculoskeletal and skin diseases, including support for training in medical schools, graduate clinical training, graduate training in epidemiology, epidemiology studies, clinical trials, and interdisciplinary research programs; and

(2) establish programs of evaluation, planning, and dissemination of knowledge related to such research and training.

INFORMATION CLEARINGHOUSE AND DATA SYSTEM

SEC. 493. (a) The Director of the Institute shall establish the National Arthritis and Musculoskeletal and Skin Diseases Data System for the collection, storage, analysis, retrieval, and dissemination of data derived for patient populations with arthritis and musculoskeletal and skin diseases, including where possible, data involving general populations for the purpose of detection of individuals with a risk of developing arthritis and musculoskeletal and skin diseases. There are authorized to be appropriated to carry out this subsection $1,000,000 for the fiscal year ending September 30, 1984, $1,500,000 for the fiscal year ending September 30, 1985, and $1,800,000 for the fiscal year ending September 30, 1986.

(b) The Director of the Institute shall establish the National Arthritis and Musculoskeletal and Skin Diseases Information Clearinghouse to facilitate and enhance, through the effective dissemination of information, knowledge and understanding of arthritis and musculoskeletal and skin diseases by health professionals, patients, and the public. There are authorized to be appropriated to carry out this subsection $1,000,000 for the fiscal year ending September 30, 1984, $1,500,000 for the fiscal year ending September 30, 1985, and $1,800,000 for the fiscal year ending September 30, 1986.

INTERAGENCY COORDINATING COMMITTEES

SEC. 494. (a) For the purpose of—

(1) better coordination of the research activities of all the national research institutes relating to arthritis, musculoskeletal and skin diseases, including sports-related disorders; and

(2) coordinating the aspects of all Federal health programs and activities relating to arthritis, musculoskeletal diseases, and skin diseases in order to assure the adequacy and technical

soundness of such programs and activities and in order to provide for the full communication and exchange of information necessary to maintain adequate coordination of such programs and activities,

the Secretary shall establish an Arthritis and Musculoskeletal Diseases Interagency Coordinating Committee and a Skin Diseases Interagency Coordinating Committee (hereafter in this section individually referred to as a 'committee').

(b) Each Committee shall be composed of the Directors (or their designees) of each of the national research institutes and divisions involved in research regarding the diseases with respect to which the Committee is established, the Chief Medical Director of the Veterans' Administration, (or the Director's designee) a medical officer designated by the Department of Defense, and representatives of all other Federal departments and agencies (as determined by the Secretary) whose programs involve health functions or responsibilities relevant to arthritis and musculoskeletal diseases or skin diseases, as the case may be. Each Committee shall be chaired by the Direcor of the National Institutes of Health (or the Director's designee). Each Committee shall meet at the call of the Chairman, but not less often than four times a year.

(c) Not later than one hundred twenty days after the end of each fiscal year, each Committee shall prepare and transmit to the Secretary, the Director of the National Institutes of Health, the Director of the Institute, and the Advisory Council a report detailing the activities of the Committee in such fiscal year in carrying out paragraphs (1) and (2) of subsection (a).

NATIONAL ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES ADVISORY COUNCIL

SEC. 495. (a) The Secretary shall establish a National Arthritis and Musculoskeletal and Skin Diseases Advisory Council to advise, consult with, and make recommendations to the Secretary with respect to the activities of the Institute relating to arthritis and musculoskeletal and skin diseases.

(b) The Advisory Council shall consist of the Secretary, who shall be chairman, the chief medical officer of the Veterans' Administration (or such officer's designee) and a medical officer designated by the Secretary of Defense, each of whom shall be ex officio members, and twelve members appointed by the Secretary without regard to the civil service laws. The twelve members appointed by the Secretary shall be leaders in the fields of basic sciences, medical sciences, education, or nursing, and individuals from the public who are knowledgeable with respect to arthritis and musculoskeletal and skin diseases. Six of the members appointed by the Secretary shall be selected from leading medical for scientific authorities who are outstanding in the study, diagnosis, or treatment of arthritis and musculoskeletal and skin diseases.

(c)(1) Each member of the Advisory Council who is appointed by the Secretary shall be appointed for a term of four years, except that—

(A) the term of office of the members first appointed shall expire, as determined by the Secretary at the time of appoint-

ment, three at the end of one year, three at the end of two years, three at the end of three years, and three at the end of four years; and

(B) any member appointed to fill a vacancy occurring prior to the expiration of the term for which the member's predecessor was appointed shall be appointed for the remainder of such term.

(2) None of the members appointed to the Advisory Council by the Secretary shall be eligible for reappointment unless a year has elapsed since the end of the prior term of such member on the council.

ARTHRITIS AND MUSCULOSKELETAL DISEASES DEMONSTRATION PROJECTS

SEC. 496. (a) The Secretary may make grants to public and private nonprofit entities to establish and support projects for the development and demonstration and methods for screening, detection, and referral for treatment of arthritis and musculoskeletal diseases, and for the dissemination of information on such methods to the health and allied health professions. Activities under such projects shall be coordinated with Federal, State, local, and regional health agencies, centers assisted under section 497, and the data system established under subsection (c).

(b) Projects supported under this section shall include—

(1) programs which emphasize the development and demonstration of new and improved methods of screening and early detection, referral for treatment, and diagnosis of individuals with a risk of developing arthritis and musculoskeletal diseases;

(2) programs which emphasize the development and demonstration of new and improved methods for patient referral from local hospitals and physicians to appropriate centers for early diagnosis and treatment;

(3) programs which emphasize the development and demonstration of new and improved means of standardizing patient data and recordkeeping;

(4) programs which emphasize the development and demonstration of new and improved methods of dissemination of knowledge about the programs, methods, and means referred to in paragraphs (1), (2), and (3) of this subsection to health and allied health professionals;

(5) programs which emphasize the development and demonstration of new and improved methods for the dissemination to the general public of information—

(A) on the importance of early detection of arthritis and musculoskeletal diseases, of seeking prompt treatment, and of following an appropriate regimen; and

(B) to discourage the promotion and use of unapproved and ineffective diagnostic, prventive treatment, and control methods for arthritis and unapproved and ineffective drugs and devices for arthritis and musculoskeletal diseases; and

(6) projects for investigation into the epidemiology of all forms and aspects of arthritis and musculoskeletal diseases, including investigations into the social, environmental, behavioral, nutritional, and genetic determinants and influences in-

volved in the epidemiology of arthritis and musculoskeletal diseases.

(c) The Director shall provide for the standardization of patient data and recordkeeping for the collection, storage, analysis, retrieval, and dissemination of such data in cooperation with projects under this section and centers assisted under section 497, and other persons engaged in arthritis and musculoskeletal disease programs.

(d) There are authorized to be appropriated to carry out this section $5,000,000 for the fiscal year ending September 30, 1984, and for each of the two succeeding fiscal years.

MULTIPURPOSE ARTHRITIS AND MUSCULOSKELETAL DISEASE CENTERS

SEC. 497. (a) The Director of the Institute shall, after consultation with the Advisory Council established pursuant to section 495, provide for the development, modernization, and operation (including staffing and other operating costs such as the costs of patient care required for research) of new and existing centers for arthritis and musculoskeletal diseases. For purposes of this section, the term 'modernization' means the alteration, remodeling, improvement, expansion, and repair of existing buildings and the provision of equipment for such buildings to the extent necessary to make them suitable for use as centers described in the preceding sentence.

(b) Each center assisted under this section shall—

(1)(A) use the facilities of a single institution or a consortium of cooperating institutions, and (B) meet such qualifications as may be prescribed by the Secretary; and

(2) conduct—

(A) basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of arthritis and musculoskeletal diseases and complications resulting from arthritis and musculoskeletal diseases, including research into implantable biomaterials and biomechanical and other orthopedic procedures;

(B) training programs for physicians, scientists, and other health and allied health professionals;

(C) information and continuing education programs for physicians and other health and allied health professionals who provide care for patients with arthritis and musculoskeletal diseases; and

(D) programs for the dissemination to the general public of information—

(i) on the importance of early detection of arthritis and musculoskeletal diseases, of seeking prompt treatment, and of following an appropriate regimen; and

(ii) to discourage the promotion and use of unapproved and ineffective diagnostic, preventive, treatment, and control methods and unapproved and ineffective drugs and devices.

A center may use funds provided under subsection (a) to provide stipends for health professionals enrolled in training programs described in paragraph (2)(B).

(c) Each center assisted under this section may conduct programs to—

(1) establish the effectiveness of new and improved methods of detection, referral, and diagnosis of individuals with a risk of developing arthritis and musculoskeletal diseases;

(2) disseminate the results of research, screening, and other activities, and develop means of standardizing patient data and recordkeeping; and

(3) develop community consultative services to facilitate the referral of patients to centers for treatment.

(d) The Director of the Institute shall, insofar as practicable, provide for an equitable geographical distribution of centers assisted under this section. The Director shall give appropriate consideration to the need for centers especially suited to meeting the needs of children affected by arthritis and musculoskeletal diseases.

(e) Support of a center under this section may be for a period of not to exceed five years. Such period may be extended by the Director of the Institute for one or more additional periods of not more than five years if the operations of such center have been reviewed by an appropriate scientific review group established by the Director and such scientific review group has recommended to the Director that support of such center under this section should be extended.

(f) There are authorized to be appropriated to carry out this section $12,000,000 for the fiscal year ending September 30, 1984, $15,000,000 for the fiscal year ending September 30, 1985, and $18,000,000 for the fiscal year ending September 30, 1986.

BIENNIAL REPORT

SEC. 498. (a) The Director of the Institute shall prepare and transmit to the Secretary, for transmission by the Secretary to the President and the Congress, a biennial report containing a description of the Institute's activities under the plan developed pursuant to section 492(b), a description of the Institute's activities to carry out the recomendations contained in the two immediately preceding annual reports prepared pursuant to section 492(c), and an evaluation of the activities of the centers supported under section 497.

(b) The first report under subsection (a) shall be transmitted by the Director to the Secretary not later than the first November 30 which occurs at least eighteen months after the date of the enactment of this section and shall relate to the two-fiscal-year period ending on the preceding September 30.

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TITLE XIII—HEALTH MAINTENANCE ORGANIZATIONS

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DEFINITIONS

SEC. 1302. [300e-1] For purposes of this title:

(1) The term "basic health services" means—

(A) physician services (including consultant and referral services by a physician);

(B) inpatient and outpatient hospital services;

(C) medically necessary emergency health services;

(D) short-term (not to exceed twenty visits), outpatient evaluative and crisis intervention mental health services;

(E) medical treatment and referral services (including referral services to appropriate ancillary services) for the abuse of or addiction to alcohol and drugs;

(F) diagnostic laboratory and diagnostic and therapeutic radiologic services;

(G) home health services; and

(H) preventive health services (including (i) immunizations, (ii) well-child care from birth, (iii) periodic health evaluations for adults, (iv) voluntary family planning services, (v) infertility services, and (vi) children's eye and ear examinations conducted to determine the need for vision and hearing correction).

Such term does not include a health service which the Secretary, upon application of a health maintenance organization, determines is unusual and infrequently provided and not necessary for the protection of individual health. The Secretary shall publish in the Federal Register each determination made by him under the preceding sentence. If a service of a physician described in the preceding sentence may also be provided under applicable State law by a dentist, optometrist, podiatrist, *clinical psychologist,* or other health care personnel, a health maintenance organization may provide such service through a dentist, optometrist, podiatrist, *clinical psychologist,* or other health care personnel (as the case may be) licensed to provide such service. For purposes of this paragraph, the term "home health services" means health services provided at a member's home by health care personnel, as prescribed or directed by the responsible physician or other authority designated by the health maintenance organization.

(2) The term "supplemental health services" means any health service which is not included as a basic health service under paragraph (1) of this section. If a health service provided by a physician may also be provided under applicable State law by a dentist, optometrist, podiatrist, *clinical psychologist,* or other health care personnel, a health maintenance organization may provide such service through an optometrist, dentist, podiatrist, *clinical psychologist,* or other health care personnel (as the case may be) licensed to provide such service.

(3) The term "member" when used in connection with a health maintenance organization means an individual who has entered into a contractual agreement, or on whose behalf a contractual arrangement has been entered into, with the organization under which the organization assumes the responsibility for the provision to such individual of basic health services and of such supplemental health services as may be contracted for.

(4) The term "medical group" means a partnership, association, or other group—

(A) which is composed of health professionals licensed to practice medicine or osteopathy and of such other licensed health professionals (including dentists, optometrists, [and podiatrists] *podiatrists, and clinical psychologists* as are necessary for the provision of health services for which the group is responsible;

(B) a majority of the members of which are licensed to practice medicine or osteopathy; and

(C) the members of which (i) as their principal professional activity engage in the coordinated practice of their profession and as a group responsibility have substantial responsibility for the delivery of health services to members of a health maintenance organization, except that this clause does not apply before the end of the forty-eight month period beginning after the month in which the health maintenance organization becomes a qualified health maintenance organization as defined in section 1310(d), or as authorized by the Secretary in accordance with regulations that take into consideration the usual circumstances of the group; (ii) pool their income from practice as members of the group and distribute it among themselves according to a prearranged salary or drawing account or other similar plan unrelated to the provision of specific health service; (iii) share medical and other records and substantial portions of major equipment and of professional, technical, and administrative staff; (iv) arrange for and encourage continuing education in the field of clinical medicine and related areas for the members of the group; and (v) establish an arrangement whereby a member's enrollment status is not known to the health professional who provides health services to the member.

(5) The term "individual practice association" means a partnership, corporation, association, or other legal entity which has entered into a services arrangement (or arrangements) with persons who are licensed to practice medicine, osteopathy, dentistry, podiatry, optomerty, *clinical psychology,* or other health profession in a State and a majority of whom are licensed to practice medicine or osteopathy. Such an arrangement shall provide—

(A) that such persons shall provide their professional services in accordance with a compensation arrangement established by the entity; and

(B) to the extent feasible, for the sharing by such persons of medical and other records, equipment, and professional, technical, and administrative staff.

(6) The term "health systems agency" means an entity which is designated in accordance with section 1515 of this Act.

(7) The term "medically underserved population" means the population of an urban or rural area designated by the Secretary as an area with a shortage of personal health services or a population group designated by the Secretary as having a shortage of such services. Such a designation may be made by the Secretary only after consideration of the comments (if any) of (A) each State health planning and development agency which covers (in whole or in part) such urban or rural area or the area in which such population group resides, and (B) each health systems agency designated for a health service area which covers (in whole or in part) such urban or rural area or the area in which such population group resides.

(8)(A) The term "community rating system" means the systems, described in subparagraphs (B) and (C), of fixing rates of payments for health services. A health maintenance organization may fix its

rates of payments under the system described in subparagraph (B) or (C) or under both such systems, but a health maintenance organization may use only one such system for fixing its rates of payments for any one group.

(B) A system of fixing rates of payment for health services may provide that the rates shall be fixed on a per-person or per-family basis and may authorize the rates to vary with the number of persons in a a family, but, except as authorized in subparagraph (D), such rates must be equivalent for all individuals and for all families of similar composition.

(C) A system of fixing rates of payment for health services may provide that the rates shall be fixed for individuals and families by groups. Except as authorized in subparagraph (D), such rates must be equivalent for all individuals in the same group and for all families of similar composition in the same group. If a health maintenance organization is to fix rates of payment for individuals and families by groups, it shall—

(i) classify all of the members of the organization into classes based on factors which the health maintenance organization determines predict the differences in the use of health services by the individuals or families in each class and which have not been disapproved by the Secretary.

(ii) determine its revenue requirements for providing services to the members of each class established under clause (i), and

(iii) fix the rates of payment for the individuals and families of a group on the basis of a composite of the organization's revenue requirements determined under clause (ii) for providing services to them as members of the classes established under clause (i).

The Secretary shall review the factors used by each health maintenance organization to establish classes under clause (i). If the Secretary determines that any such factor may not reasonably be used to predict the use of the health services by individuals and families, the Secretary shall disapprove such factor for such purpose.

(D) The following differentials in rates of payments may be established under the systems described in subparagraphs (B) and (C):

(i) Nominal differentials in such rates may be established to reflect differences in marketing costs and the different administrative costs of collecting payments from the following categories of members:

(I) Individual members (including their families).

(II) Small groups of members (as determined under regulations of the Secretary).

(III) Large groups of members (as determined under regulations of the Secretary).

(ii) Nominal differentials in such rates may be established to reflect the compositing of the rates of payment in a systematic manner of accommodate group purchasing practices of the various employers.

(iii) Differentials in such rates may be established for members enrolled in a health maintenance organization pursuant to a contract with a governmental authority under section 1079 or 1086 of title 10, United States Code, or under any other governmental program (other than the health benefits pro-

gram authorized by chapter 89 of title 5, United States Code) or any health benefits program for employees of States, political subdivision of States, and other public entities.

(9) The term "non-metropolitan area" means an area no part of which is within an area designated as a standard metropolitan statistical area by the Office of Management and Budget and which does not contain a city whose population exceeds fifty thousand individuals.

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